

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

IN RE PHARMACEUTICAL INDUSTRY)	
AVERAGE WHOLESALE PRICE)	MDL No. 1456
LITIGATION)	
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THIS DOCUMENT RELATES TO)	CIVIL ACTION: 01-CV-12257-PBS
ALL CLASS ACTIONS)	Judge Patti B. Saris
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)	<u>FILED UNDER SEAL</u>

**AMENDED MASTER CONSOLIDATED CLASS ACTION COMPLAINT MODIFIED
PER THE COURT'S INSTRUCTION AT THE NOVEMBER 21, 2003 HEARING
WITH AMGEN AMENDMENTS**

TABLE OF CONTENTS

	Page
I. INTRODUCTION	1
II. JURISDICTION AND VENUE	7
III. PARTIES	8
A. Plaintiffs	8
B. Defendants	14
1. Abbott	15
2. Amgen	15
3. AstraZeneca	16
4. The Aventis Group (Aventis, Pharma, Hoechst and Behring)	17
5. Baxter	18
6. Bayer	19
7. The Boehringer Group (Boehringer, Ben Venue, Bedford)	19
8. Braun	20
9. The BMS Group (Oncology Therapeutics; Apothecon)	21
10. Dey, Inc.	22
11. The Fujisawa Group (Fujisawa Healthcare, Fujisawa USA)	23
12. The GSK Group (GlaxoSmithKline, SmithKline Beecham, Glaxo Wellcome)	24
13. Hoffman-LaRoche, Inc.	25
14. Immunex	25
15. The Johnson & Johnson Group (J&J, Centocor, Janssen, NcNeil, Ortho)	26
16. Novartis	27
17. Pfizer, Inc.	28

18.	The Pharmacia Group (Pharmacia and Pharmacia & Upjohn).....	28
19.	The Schering-Plough Group (Schering Plough & Warrick).....	30
20.	The Sicor Group (Sicor and Gensia).....	30
21.	TAP	31
22.	Watson	32
23.	Together Rx	32
IV.	GENERAL ALLEGATIONS APPLICABLE TO ALL DEFENDANTS.....	32
A.	The AWP System.....	33
B.	The Defendant Drug Manufacturers Commit AWP Fraud to Increase Market Share For Their Drugs Covered by Medicare Part B	35
1.	The Medicare Insurance Program.....	35
2.	Congressional and Other Federal Investigations and Actions	38
3.	Certain of the Defendants Drug Manufacturers' Fraudulent Conduct Within the Medicare Part B Program	40
a.	Artificially Inflating AWPs.....	40
b.	Improper Use of Free Samples	41
c.	Other Hidden and Improper Inducements and Price Reductions.....	41
C.	The Defendant Drug Manufacturers' Use of AWP Fraud to Increase and Maintain the Price of Drugs Outside of the Medicare Part B Context.....	42
D.	The Defendant Drug Manufacturers' Use of AWP Fraud to Increase and Maintain Volume and Market Share For Generic and Multi-Source Drugs	45
E.	Defendants' Concealment of the Truth.....	50
F.	Tolling of Applicable Statutes of Limitation	51
V.	EXAMPLES OF SPECIFIC UNLAWFUL CONDUCT	52
A.	Abbott	52
1.	Abbott Has Been The Target of Government Investigations.....	54
2.	Abbott Controls the Published AWP for Its Products	55

3.	Abbott's AWP Manipulation Benefited Providers at the Expense of the Class	55
4.	Specific Abbott AWPs Documented by the DOJ	56
5.	Additional Evidence Concerning Vancomycin	57
6.	Additional Evidence for Amikacin	58
7.	Inflated AWPs From Abbott Price Lists.....	58
B.	Amgen.....	Error! Bookmark not defined.
1.	Amgen's Definition and Understanding of AWP Error! Bookmark not defined.	
2.	Amgen Controls the Published AWP for Its Products Error! Bookmark not defined.	
3.	Amgen's AWP Manipulation Benefited Providers at the Expense of the Class	Error! Bookmark not defined.
4.	Amgen Provided Free Goods and Other Incentives Error! Bookmark not defined.	
5.	Amgen Concealed Its AWP Manipulation Error! Bookmark not defined.	
C.	AstraZeneca	60
1.	AstraZeneca Has Been the Target of a Government Investigation.....	71
2.	AstraZeneca's Definition and Understanding of AWP	71
3.	AstraZeneca Controls the Published AWP for Its Products	72
4.	AstraZeneca's AWP Manipulation Benefited Providers at the Expense of the Class	72
D.	The Aventis Group (Aventis, Pharma, Hoechst and Behring).....	78
1.	Aventis Has Been the Target of Government Investigations.....	80
2.	Aventis' Definition and Understanding of AWP	80
3.	Aventis Controls the Published AWP for Its Products	81
4.	Aventis' AWP Manipulation Benefited Providers at the Expense of the Class.....	81
5.	Specific Aventis AWPs Documented by the DOJ.....	83
6.	Additional Evidence Concerning Anzemet	84

7.	Additional Evidence Concerning Gammar	85
8.	Inflated AWPs From Aventis' Price Lists	86
9.	Aventis Concealed its AWP Manipulation	87
E.	Baxter	87
1.	Baxter Has Been the Target of Government Investigations	89
2.	Baxter's Definition and Understanding of AWP	89
3.	Baxter Controls the Published AWP for its Products	90
4.	Baxter's AWP Manipulation Benefited Providers at the Expense of the Class	90
5.	Specific Baxter AWPs Documented by the DOJ.....	91
6.	Evidence Concerning Gammagard S/D (immune globulin solution)	92
7.	Inflated AWPs From Baxter's Price Lists	92
8.	Baxter Provided Free Goods and Other Incentives.....	94
F.	Bayer	94
1.	Bayer Has Been the Target of Government Investigations	95
2.	Bayer Controls the Published AWP for Its Products	96
3.	Bayer's AWP Manipulation Benefited Providers at the Expense of the Class	96
4.	Specific Bayer AWPs Documented by the DOJ.....	97
5.	Inflated AWPs From Bayer's Price Lists.....	98
6.	Bayer Provided Free Goods and Other Incentives.....	98
7.	Bayer Concealed Its AWP Manipulation.....	99
G.	The Boehringer Group	99
1.	The Boehringer Group Has Been the Target of Government Investigations	100
2.	The Boehringer Group Controls the Published AWP for Its Products.....	100

3.	Specific Boehringer AWPs Documented by the DOJ	103
4.	Inflated Boehringer Group AWPs From Bedford's Price Lists.....	104
H.	B. Braun	104
1.	B. Braun Has Been the Target of Government Investigations.....	105
2.	B. Braun's Understanding of AWP	105
3.	B. Braun Controls the Published AWP for Its Products	106
4.	B. Braun's AWP Manipulation Benefited Providers at the Expense of the Class	107
5.	Specific B. Braun AWPs Documented by the DOJ	108
6.	Inflated AWPs From B. Braun Price Lists.....	109
I.	The BMS Group (Bristol-Myers, OTN and Apothecon)	110
1.	The BMS Group Has Been the Target of Government Investigations	111
2.	The BMS Group Controls the Published AWP for Its Products.....	112
3.	BMS's AWP Manipulation Benefited Providers at the Expense of the Class.....	113
4.	Specific BMS AWPs Documented by the DOJ	113
5.	Other AWPs Related to VEPESID (etoposide)	114
6.	Other AWPs Related to Blenoxane.....	114
7.	The BMS Group Provided Free Goods and Other Incentives	115
J.	Dey	117
1.	Dey Has Been the Target of Government Investigations	117
2.	Dey Controls the Published AWP for Its Products.....	119
3.	Dey's AWP Manipulation Benefited Providers at the Expense of the Class.....	120
4.	Specific Dey AWPs Documented by the DOJ.....	121
5.	Inflated Dey AWPs From Dey's Price Lists.....	121
6.	Dey Provided Free Goods and Other Incentives.....	122

7.	Dey Has Concealed Its AWP Manipulation	123
K.	The Fujisawa Group (Fujisawa Pharmaceutical, Fujisawa Healthcare, Fujisawa USA).....	123
1.	Fujisawa Has Been the Target of Government Investigations.....	125
2.	Fujisawa Controls the Published AWP for Its Products	125
3.	Fujisawa's AWP Manipulation Benefited Providers at the Expense of the Class	125
4.	Specific Fujisawa AWPs Documented by the DOJ	126
5.	Inflated AWPs From Fujisawa Price Lists.....	127
L.	The GSK Group (GlaxoSmithKline, SmithKline Beecham, Glaxo Wellcome).....	129
1.	The GSK Group Has Been the Target of Government Investigations	131
2.	The GSK Group's Definition and Understanding of AWP	132
3.	The GSK Group Controls the Published AWP for Its Products	132
4.	The GSK Group's AWP Manipulation Benefited Providers at the Expense of Plaintiffs and the Class.....	133
5.	Glaxo's Zofran®	134
6.	SKB's Kytril	139
7.	General Counsel Correspondence Between Glaxo and SKB	140
8.	Other Improper Incentives	142
9.	Specific GSK Group AWPs Documented by the DOJ	143
M.	Hoffman-LaRoche	144
1.	Hoffman-LaRoche Controls the Published AWP for Its Products	144
2.	Inflated Hoffman-LaRoche AWPs From Hoffman LaRoche Price Lists.....	145
3.	Hoffman-LaRoche Provided Free Goods and Other Incentives	145
N.	Immunex	145
1.	Immunex Has Been the Target of Government Investigations.....	146

2.	Immunex Definition and Understanding of AWP	146
3.	Immunex Controls the Published AWP for its Products	146
4.	Immunex's AWP Manipulation Benefited Providers at the Expense of the Class	147
5.	Specific Immunex AWPs Documented by the DOJ	149
6.	Inflated AWPs From Immunex Price Lists.....	150
7.	Immunex Concealed Its AWP Manipulation.....	150
O.	The Johnson & Johnson Group (J&J, Centocor and Ortho)	150
1.	The Johnson & Johnson Group Has Been the Target of Government Investigations	153
2.	J&J Concealed Its AWP Manipulation.....	155
P.	Novartis.....	156
1.	Novartis Has Been the Target of Government Investigations	157
2.	Inflated Novartis AWPs From Novartis Price Lists	157
Q.	Pfizer	158
R.	The Pharmacia Group (Pharmacia and P&U).....	160
1.	The Pharmacia Group Has Been the Target of Government Investigations	161
2.	Pharmacia's Definition and Understanding of AWP.....	161
3.	The Pharmacia Group Controls the Published AWP for Its Products.....	162
4.	The Pharmacia Group's AWP Manipulation Benefited Providers at the Expense of the Class	162
5.	Specific Pharmacia AWPs Documented by the DOJ	165
6.	Inflated Pharmacia AWPs From Pharmacia's Price Lists	167
7.	The Pharmacia Group Provided Free Goods and Other Incentives	168
S.	The Schering-Plough Group (Schering-Plough and Warrick).....	169
1.	The Schering Plough Group Has Been the Target of Government Investigations	171

2.	The Schering Plough Group Controls the Published AWP for Its Products.....	172
3.	The Schering Plough Group's AWP Manipulation Benefited Providers at the Expense of the Class	173
4.	The DOJ Specifically Documented AWP Inflation for Albuterol Sulfate.....	175
5.	The Schering Plough Group Provided Free Goods and Other Incentives	176
T.	The Sicor Group (Sicor, Gensia and Gensia Sicor)	176
1.	The Sicor Group Has Been the Target of Government Investigations	177
2.	The Sicor Group Controls the Published AWP for Its Products.....	177
3.	The Sicor Group's AWP Manipulation Benefited Providers at the Expense of the Class	178
4.	Specific Sicor Group AWPs Documented by the DOJ.....	180
5.	Inflated Sicor Group AWPs From the Sicor Group's Price Lists.....	180
6.	The Sicor Group Provided Free Goods and Other Incentives	181
U.	TAP	182
1.	TAP Has Been the Target of Government Investigations	182
2.	TAP Controls the Published AWP for Its Products.....	184
3.	TAP's AWP Manipulation Benefited Providers at the Expense of the Class.....	184
4.	TAP Provided Free Goods and Other Incentives.....	184
5.	TAP Concealed Its AWP Manipulation.....	186
V.	Warrick	186
W.	Watson	187
1.	Watson Has Been the Target of Government Investigations.....	188
2.	Watson's Definition and Understanding of AWP	188
3.	Watson Controls the Published AWP for Its Products	188

4.	Watson's AWP Manipulation Benefited Providers at the Expense of the Class	189
5.	Specific Watson AWPs Documented by the DOJ	189
6.	Inflated Watson AWPs From Watson's Price Lists.....	190
7.	Watson Provided Free Goods and Other Incentives	191
8.	Watson Concealed Its AWP Manipulation	191
VI.	DIRECT DAMAGE SUSTAINED BY PLAINTIFFS AND THE MEMBERS OF THE AWP CLASS	191
VII.	CERTAIN DEFENDANTS USE AWP TO ENGAGE IN A SCHEME TO FIX PRICES – THE TOGETHER CARD SCHEME	192
A.	The Formation of the Together Card Conspiracy	192
B.	The Drug Discount Card Response to the Lack of Medicare Drug Coverage and the Underpinnings of the Together Card Scheme.....	193
1.	GSK Orange Card	194
2.	Novartis Care Card	196
C.	Implementation of the Together Rx Card Program	197
D.	Marketing of the Together Card Program.....	201
E.	The Together Card Defendants' Conspiracy to Fix the AWP Spread of the Together Card Drugs	203
VIII.	CLASS ACTION ALLEGATIONS FOR THE AWP PAYOR SCHEME	208
IX.	CLASS ACTION ALLEGATIONS FOR THE TOGETHER CARD SCHEME	211
COUNT I	VIOLATIONS OF 18 U.S.C. § 1962(c) (AGAINST DEFENDANT DRUG MANUFACTURERS IDENTIFIED HEREIN FOR UNLAWFUL CONDUCT ASSOCIATED WITH MEDICARE PART B COVERED DRUGS).....	210
COUNT II	VIOLATIONS OF 18 U.S.C. § 1962(c) (AGAINST DEFENDANT DRUG MANUFACTURERS IDENTIFIED HEREIN).....	241
COUNT III	DECLARATORY AND OTHER RELIEF PURSUANT TO 28 U.S.C. §§ 2201, 2002	271
COUNT IV	VIOLATIONS OF CONSUMER PROTECTION STATUTES	272

COUNT V CLAIM FOR INJUNCTIVE RELIEF UNDER SECTION 16 OF THE CLAYTON ACT ARISING FROM THE TOGETHER CARD CONSPIRACY	274
COUNT VI CLAIM FOR VIOLATION OF SHERMAN ACT, 15 U.S.C. § 1 ON BEHALF OF NATIONWIDE END PAYOR TOGETHER CARD CLASS	275
COUNT VII CLAIM FOR VIOLATION OF THE ANTITRUST STATUTES OF THE INDIRECT PURCHASER STATES ON BEHALF OF INDIRECT PURCHASER STATES END PAYOR TOGETHER CARD CLASS	277
COUNT VIII VIOLATIONS OF 18 U.S.C. § 1962(c)-(d) (AGAINST THE TOGETHER CARD DEFENDANTS FOR UNLAWFUL CONDUCT ASSOCIATED WITH TOGETHER RX)	281
COUNT IX CIVIL CONSPIRACY (AGAINST ALL DEFENDANTS IDENTIFIED HEREIN FOR CONSPIRING WITH PBMs)	286
COUNT X CIVIL CONSPIRACY (AGAINST THE TOGETHER CARD DEFENDANTS).....	297
X. PRAYER FOR RELIEF	304
XI. DEMAND FOR JURY TRIAL	305

Plaintiffs, by and through their counsel, upon personal knowledge as to their own acts and beliefs, and upon information and belief as to all other matters based upon the investigations of counsel, allege as follows: This version of the AMCC adds allegations as to the relationship between each plaintiff and the AWP scheme described herein as requested by the Court on November 21, 2003.¹

I. INTRODUCTION

1. This case is brought by Plaintiffs as a proposed class action on behalf of consumers, self-insured employers, health and welfare plans, health insurers and other end payors for prescription drugs (the “Class”) against certain pharmaceutical companies (referred to as the “Defendant Drug Manufacturers”).

2. For the last decade, the Defendant Drug Manufacturers have conspired with others in the pharmaceutical distribution chain, including but not limited to physicians and hospitals (hereafter “medical providers” or “providers”), pharmacy benefit managers (“PBMs”) and various publishing entities, to collect inflated prescription drug payments from Plaintiffs and the Class.

3. More specifically, the Defendant Drug Manufacturers report to trade publications a drug price – the Average Wholesale Price (or “AWP”) – that for many drugs is deliberately set far above the prices that these drugs are available in the marketplace. The AWPs for these drugs are deliberately false and fictitious and created solely to cause Plaintiffs and the Class members to overpay for drugs. Because all drugs administered under Medicare Part B are priced based on the published AWPs, the Defendant Drug Manufacturers inflate AWP reimbursement rates to enable providers and others to make secret profits through overcharges to patients, their insurers

¹ The complaint also fixes a typo that carried from the MCC to the AMCC in Count I. The title stated that the claims were asserted as to Medicare Part B Drugs. However, the body of the count does not limit Count I to Part B drugs and it was not intended to be limited in that fashion. Count I covers all AWPs in Appendix A in any fashion they were sold in the distribution chain outside of the PBM context.

and other end payors. This, in turn, motivates the providers to sell and administer the drugs with the most inflated AWPs, resulting in increased market share and profit for the Defendant Drug Manufacturers and inflated payments for drugs by individual patients (through co-pays or direct payments), health plans and insurers.

4. For drugs reimbursed by Medicare Part B (which generally, but not always, require administration in a provider's office), the health care providers administer the drugs and are reimbursed by Medicare based on the inflated AWP. Thus, the providers benefit by pocketing the "spread" between the AWP and the actual cost that they pay for the drugs, and the Defendant Drug Manufacturers benefit by increasing the sales of their drugs that are covered by Medicare Part B ("Covered Drugs") and by increasing their market share. In some cases, the Defendant Drug Manufacturers also provide chargebacks, rebates, hidden price discounts and/or other unlawful financial inducements, including free samples, to further increase the provider's spread and, therefore, their incentive to prescribe a particular Defendant Drug Manufacturer's product. Those discounts are not used by the Defendant Drug Manufacturers in calculating the published AWPs, resulting in their inflation.

5. The use of AWP is not limited to Medicare reimbursement. Rather, AWP is a benchmark from which hundreds of drug prices are derived in transactions throughout the pharmaceutical distribution chain. For "Part B covered drugs" administered outside of the Medicare Part B context, non-Medicare patients and health plans pay for these drugs based on the inflated AWP with an intermediary (for example, a pharmacy benefit manager) pocketing the "spread" between the AWP and the actual cost that the intermediaries pay for these drugs. And similar to the benefit that the Defendant Drug Manufacturers obtain through the AWP scheme for Part B drugs, the Defendant Drug Manufacturers also benefit from the AWP scheme with respect to these drugs by increasing the sales of their particular AWP-inflated drugs and their market share for those drugs. The use of AWP as a benchmark for reimbursement is also not

limited to Part B drugs being administered outside of Medicare, but extends to thousands of other drugs as well. And again, with respect to these non-Part B drugs, it is the end payor, be it a health plan or private insurer, that pays the inflated amount. All others in the distribution chain, be they wholesalers, pharmacies or pharmacy benefit manufacturers, benefit from the spread between AWP and actual costs.

6. Thus, in a perversion of the type of competitive behavior expected in a market not subject to illegal manipulation, the Defendant Drug Manufacturers often promote their drugs not based on lower prices, but by the use of reimbursement rates based on a fictitious and inflated AWP that allows purchasers and intermediaries (including providers and PBMs) to make inflated profits – and the Defendant Drug Manufacturers to increase their market share – at the expense of Plaintiffs and the Class. The Class, as further defined below, consists of all purchasers of drugs whose AWPs were inflated (“AWP End Payor Class”).

7. The Defendant Drug Manufacturers also caution providers and other intermediaries that the success of the high profit scheme will be jeopardized if anyone discloses the significantly lower prices actually paid for the drugs (allowing the scheme to be concealed and to continue). All Defendants actively conceal, and caused others to conceal, information about the true pricing structure for the prescription drugs, including the fact that the AWPs for the drugs are deliberately overstated. And, all those in the distribution chain also conceal the rebates, free samples, educational grants and other economic rewards which they receive, but which are not reflected in calculating AWP.

8. The harm flowing from the misuse of the AWP does not stop with the aforementioned scheme. As detailed herein, in a new section of the Complaint, certain of the Defendants used these AWPs for an additional purpose, as part of a scheme and unlawful agreement to fix the AWP spread of drug prices under the guise of offering seniors a discount on their drugs. Thus, in new sections of the Complaint, plaintiffs charge certain pharmaceutical

manufacturers with price fixing in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1, and in violation of applicable state antitrust and consumer protection laws. These certain defendant manufacturers (identified below as the “Together Card Defendants”) participate in the “Together Rx Card Program” (“Together Rx”), a drug discount card program commenced in 2002 that ostensibly makes available a single drug discount card to elderly poor Americans to enable them to obtain substantial discounts for approximately 170 brand name and generic drugs.

9. In fact, the Together Card Defendants have not offered *bona fide* discounts off of *bona fide* prices, but instead used the Together Rx Card Program to raise, fix and maintain the end payor reimbursement rates, costs and margins for scores of their popular drugs. The Together Card Defendants conspired and agreed to restrain trade both by agreeing to increase the AWP for scores of drugs that were part of the Together Rx Card Program, and by increasing the related “spread,” between the AWP and the posted wholesale acquisition cost or “WAC” for those drugs.

10. The Together Card Defendants have caused widespread damage. As to about one-half million Together Rx Card enrollees, the Together Card Defendants gave with one hand but secretly took with another, duping them with the belief that they were receiving real discounts off real prices when in fact they had agreed to raise their AWPs prior to commencement of the Together Rx Card Program. Thus the actual prices paid by these consumers is higher than what they would have paid but for this conspiracy. As to the broader public of prescription drug end payors (such as self-insured employers, health plans and consumers who reimburse or pay for their drugs based upon the average wholesale price), and who were purchasing drugs covered by the Together Rx Card outside of that program, by agreeing to raise AWPs, the Together Card Defendants caused hundreds of millions of dollars of unlawfully imposed expenditures.

11. In response to the Court's Order on the motion to dismiss, plaintiffs have prepared a list of each of the specific drugs that are the subject of the claims herein. This list is attached as Exhibit A to the Complaint. The drugs identified in Exhibit A will be referred to herein as the AWP Inflated Drugs ("AWPID" or "AWPIDs"). And, in Appendix A, plaintiffs identify the AWP that is the subject of this Complaint for each drug currently at issue pursuant to this Court's Order. Appendix B details which AWPIDs were purchased by each plaintiff.

12. Count I of the Complaint is asserted on behalf of a class of all persons or entities who purchased or were reimbursed for an AWPID during the class period ("the AWP Payor Class") and asserts claims under 18 U.S.C. § 1962(c) for violating RICO. In this Count, plaintiffs claim that the Defendant Drug Manufacturers engaged in an illegal pattern of racketeering wherein each manufacturer formed a separate association-in-fact enterprise with each of the companies that published their inflated AWPs, and that each manufacturer conducted the affairs of each such enterprise. *Infra* at 210.

13. In Count II of the Complaint, plaintiffs on behalf of the AWP End Payor Class assert claims under 18 U.S.C. § 1962(c) against the Defendant Drug Manufacturers alleging that they engaged in a pattern of racketeering via each manufacturer's separate association-in-fact enterprise with each of the four major pharmacy benefit manufacturers ("PBMs"), and that each manufacturer conducted the affairs of its PBM enterprises. *Infra* at 241.

14. Count III is asserted by the AWP End Payor Class and seeks declaratory relief declaring the AWP practices described herein to be illegal. *Infra* at 271.

15. Count IV is brought by the AWP End Payor Class on behalf of consumers alleging that the AWP inflation scheme violates the consumer protection laws of various states. *Infra* at 272.

16. Count V is brought on behalf of a Nationwide End Payor Together Card Class (further defined below) and seeks declaratory and injunctive relief under Section 16 of the

Clayton Act. Count V seeks, among other things, a judgment: (i) adjudicating and declaring that the Together Card Defendants have violated Section 1 of the Sherman Act by unlawfully raising and maintaining the applicable reimbursement price, or average wholesale price, in relation to the wholesale acquisition cost to create an increased “spread,” (ii) enjoining the Together Card Defendants from failing to reverse the increased rates and spread margins imposed by them during the conspiracy period, (iii) enjoining them from failing to disclose fully and accurately the true Together Rx Card discounts available to Together Rx Card enrollees; and (iv) otherwise requiring the Together Card Defendants to cease and desist from further violations of the applicable laws. *Infra* at 274.

17. Count VI is brought by the Nationwide End Payor Together Card Class pursuant to Section 1 of the Sherman Act, and seeks damages for the artificial inflation in the AWP of Together Card Drugs as a result of the Together Card Defendants restraint of trade. *Infra* at 275.

18. Count VII is brought by the Indirect Purchaser States End Payor Together Card Class for payors in states that have “indirect purchaser statutes,” and is brought as an alternative count to Count V, on behalf of those who paid inflated prices for Together Card Drugs whose prices were artificially inflated as a result of the Together Card Defendants restraint of trade. *Infra* at 277.

19. Count VIII is brought by the Nationwide End Payor Together Card Class under RICO, alleging that the Together Card Defendants conducted the affairs of an enterprise they created and controlled, Together Rx, LLC, through a pattern of racketeering. The effect of this conduct was to injure all those who purchased drugs that were part of the Together Rx Card program. *Infra* at 281.

20. Count IX is brought by the AWP End Payor Class against various Defendant Drug Manufacturers for engaging in a series of separate civil conspiracies with each of the pharmacy benefit manufacturers to artificially inflate AWPs. *Infra* at 286.

21. Count X is brought by the Nationwide End Payor Together Card Class asserting a civil conspiracy claim against the Together Card Defendants. *Infra* at 297.

II. JURISDICTION AND VENUE

22. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1331 because this action arises under the laws of the United States, 18 U.S.C. § 1964(c), and because this action alleges violations of the Racketeer Influenced and Corrupt Organizations Act (“RICO”), 18 U.S.C. §§ 1961-1968. This Court also has subject matter jurisdiction under 15 U.S.C. § 1. The Court also has diversity jurisdiction on Counts IX and X pursuant to 28 U.S.C. § 1332(a) as there is diversity between plaintiff Board of Trustees of Carpenters and Millwrights of Houston and Vicinity Welfare Trust Fund and each Defendant, and the amount in controversy exceeds \$75,000. Those claims are asserted only on behalf of this plaintiff as the named plaintiff.

23. The Court has supplemental jurisdiction over the state law claims pursuant to 28 U.S.C. § 1337. To the extent necessary, the District Court should retain jurisdiction over all parties pursuant to 28 U.S.C. § 1337 as the claims against all parties are related to the claims upon which original jurisdiction is based.

24. A substantial part of the events or omissions giving rise to the claims in this action occurred in this judicial District, and Defendants may be found within this judicial District. Venue is proper in this jurisdiction under 28 U.S.C. § 1391 and 18 U.S.C. § 1965. Defendants implemented their fraudulent marketing scheme in this District, as well as nationwide, through providers and sales representatives who reside or transact business in this District and thereby affected Class Members, who similarly reside or transact business in this District.

25. The Judicial Panel on Multidistrict Litigation has, by Order dated April 30, 2002, ordered all related cases in the *In re: Pharmaceutical Industry Average Wholesale Price*

Litigation, MDL Docket Number 1456, transferred to the District of Massachusetts for coordinated or consolidated pre-trial proceedings.

III. PARTIES

A. Plaintiffs

26. Plaintiff Board of Trustees of Carpenters and Millwrights of Houston and Vicinity Welfare Trust Fund (“CMHV”) is an employee welfare benefit plan and employee benefit plan established and maintained pursuant to Section 302(c)(5) of the Labor Management Relations Act (“LMRA”), 29 U.S.C. § 186(c)(5), and as defined by §§ 1002(1) and (3) of the Employee Retirement Income Security Act (“ERISA”), 29 U.S.C. § 1001, *et seq.*, for the purpose of providing health benefits to eligible participants and beneficiaries. As such, CMHV is a legal entity entitled to bring suit in its own name pursuant to 29 U.S.C. § 1132(d). CMHV maintains its principal place of business at 9555 West Sam Houston Parkway South, Suite 400, Houston, Texas. During the Class Period, Carpenters Welfare Trust Fund has been billed for and paid charges for Covered Drugs and otherwise made payments for drugs outside of the Medicare Part B context based on published AWPs. These drugs are identified in Appendix B. During the period relevant to the complaint, CMHV used an administrator to provide medical and drug benefits to its members. CMHV’s administrator contracted directly with a PBM to provide pharmacy services to CMHV participants. By contract, all of CMHV’s drug purchases were directly and expressly tied to AWP. CMHV paid for brand named drugs in both the retail and mail order context based on AWP minus a fixed percentage. For generic drugs in the retail context CMHV paid based upon MAC, which itself was tied to AWP and in the mail order context CMHV’s generic purchases were made at either MAC or AWP minus a fixed percentage. By contract, the AWP used to determine prices was based on that published by “First Databank Blue Book.”

27. Plaintiff Teamsters Health & Welfare Fund of Philadelphia and Vicinity (“THWF”) is an employee welfare benefit plan and employee benefit plan established and maintained pursuant to Section 302(c)(5) of the LMRA, and is an employee welfare benefit plan established and maintained pursuant to §§ 1002(1) and (3) of ERISA, for the purpose of providing health benefits to eligible participants and beneficiaries. As such, THWF is a legal entity entitled to bring suit in its own name pursuant to 29 U.S.C. 1132(d). THWF maintains its principal place of business at Fourth & Cherry Streets, Philadelphia, Pennsylvania 19106. It provides comprehensive health coverage for over 28,000 participants and beneficiaries in parts of Pennsylvania, New Jersey and Delaware. During the Class Period, THWF has been billed for and paid charges for AWPs. THWF also made payments for drugs outside of the Medicare Part B context based on published AWPs. All drugs covered by this Complaint purchased by this plaintiff are identified in Appendix B. THWF uses the services of a PBM to administer its prescription drug program. Based upon its contracts it pays for brand name drugs at AWP minus a fixed percentage, and pays for generics based on MAC, which is itself based on AWP. It also pays for certain drugs outside the PBM context and does so based on AWP.

28. Plaintiff Twin Cities Bakery Workers Health and Welfare Fund (“TCBW”) is a jointly administered Taft-Hartley Fund established and maintained pursuant to Section 302(c)(5) of the LMRA, and is an employee welfare benefit plan established and maintained pursuant to ERISA, for the purpose of providing health benefits to eligible participants and beneficiaries. TCBW maintains its principal place of business in Eagan, Minnesota. As such, TCBW is a legal entity entitled to bring suit in its own name pursuant to 29 U.S.C. § 1132(d). TCBW provides health benefits, including prescription drug benefits, to approximately 2000 active participants, and their spouses and dependents. During the Class Period, TCBW has been billed for and paid charges for AWPs. TCBW also made payments for drugs outside of the Medicare Part B context based on published AWPs. The drugs purchased by TCBW at issue in this litigation are

identified in Appendix B. TCBW contracts with a third-party administrator for administration of its pharmacy and medical benefits programs. This administrator in turn contracts with pharmacies and reimburses the pharmacies based upon published AWPs. For example, a typical agreement with a pharmacy providing services to TCBW members provides that reimbursement is at “AWP minus 10%.” It further provides that the AWP is determined by Medispan. As for generics, reimbursement is based on MAC, which in turn is derived from AWP.

29. Plaintiff United Food and Commercial Workers Unions and Employers Midwest Health Benefits Fund (“UFCW”) is an employee welfare benefit plan and employee benefit plan maintained pursuant to Section 302(c)(5) of the LMRA, and is an employee welfare benefit plan established and maintained pursuant to ERISA, for the purpose of providing health benefits to eligible participants and beneficiaries. UFCW maintains its principal place of business in Cook County, Illinois. During the Class Period, UFCW has been billed for and paid charges for AWPs, including: Abbott’s sodium chloride, gentamicin sulfate, furosemide, heparin lock flush and dextrose; Baxter’s sodium chloride and dextrose; Bedford’s leucovorin calcium; Sicor’s leucovorin calcium; Pharmacia’s methylprednisolone sodium; Braun’s sodium chloride; Aventis’ Furosemide; Immunex’ leucovorin calcium and Johnson & Johnson’s Remicade. UFCW also made payments for drugs outside of the Medicare Part B context based on published AWPs. All of UFCW drugs that are at issue in the Complaint are identified in Appendix B. From December 2000 to the present, UFCW has contracted with a PBM to administer the drug program for its members. For brand name drugs its contract expressly provides that reimbursement is at “AWP less 13%.” For generic drugs its reimbursement is also based on AWP. Prior to December 2000, UFCW contracted with pharmacies for the payment of purchases of pharmaceutical drugs by its members and beneficiaries at an estimated acquisition cost based on the AWPs (less a specified percentage) published by the manufacturers in Medispan. Further, UFCW has paid and continues to pay for Medicare Part B drug coverage to

the extent it is not fully covered by Medicare. Typically, 20% of a Part B bill would not be covered, and is paid by UFCW.

30. Plaintiff Philadelphia Federation of Teachers Health and Welfare Fund (“PFTHW”) is a voluntary employee benefits plan organized pursuant to § 501(c) of the Internal Revenue Code for the purpose of providing health benefits to eligible participants and beneficiaries. PFTHW maintains its principal place of business in Philadelphia, Pennsylvania. PFTHW provides health benefits, including prescription drug benefits, to approximately 20,000 active participants, and their spouses and dependents. During the class period, PFTHW has been billed for and paid charges for covered drugs and otherwise made payments for drugs outside of the Medicare Part B context based on published AWPs. These drugs are identified in Appendix B. During the period relevant to this Complaint PFTHW used a PBM to provide prescription services for its members. At all times its payment formula for both brand name and generic drugs was expressly tied to AWP.

31. Plaintiff Man-U Service Contract Trust Fund (“Man-U Service Fund”) is a trust fund established and maintained pursuant to Section 302(c)(5) of the Labor Management Relations Act, 29 U.S.C. § 186(c)(5), and is an employee benefit plan established and maintained pursuant to the Employee Retirement Income Security Act, 29 U.S.C. § 1001, *et seq.*, for the purpose of providing health benefits, including prescription drug coverage, to eligible participants and beneficiaries. The Man-U Service Fund maintains its principal place of business at 4600 Powder Mill Road, Suite 100, Beltsville, Maryland 20705. The Man-U Service Fund provides comprehensive health coverage, including prescription drug coverage, for approximately 1,200 participants and beneficiaries located in Maryland, Delaware, Virginia, North Carolina, Pennsylvania and Washington, D.C. All of Man-U Service Fund’s drugs at issue in the Complaint are identified in Appendix B. Plaintiff Man-U Service Fund utilizes the services of a PBM and all of its contracts provide that its drug purchases are directly based on

AWP. For example, for drugs purchased through the pharmacy, its contract provides for payment at “AWP – 16%,” and for mail-order drugs, “AWP – 23%.”

32. Plaintiff Vermont Public Interest Research Group (“VPIRG”) has been Vermont’s leading watchdog and advocacy group since 1972. It is located at 141 Main Street, Ste. 6, Montpelier, Vermont. During the Class Period, VPIRG’s members purchased prescription pharmaceuticals manufactured and/or distributed by the Defendant Drug Manufacturers and made inflated payments or co-payments based in whole or in part on published AWPs, and were injured by the illegal conduct alleged herein. For example, Ms. Elizabeth Ryan Cole of Thetford, Vermont, an active VPIRG member, purchased the Johnson & Johnson Group’s drug Retin-A based in whole or in part upon the published AWP and Ms. Dawn Taylor of Hinesburg, Vermont, an active VPIRG member, purchased BMS’s drug Plavix in whole or in part based upon Defendants’ published AWP. As an unincorporated association, VPIRG has standing to pursue this action under Fed. R. Civ. P. 17(b)(1). VPIRG appears in this action for purposes of seeking declaratory, injunctive and other non-monetary relief pursuant to 28 U.S.C. §§ 2201, 2202, §16 of the Clayton Act and any other applicable statute.

33. Plaintiff Wisconsin Citizen Action (“WCA”) is the state’s premiere public interest organization with 53,000 individual members and 250 affiliate organizations. It is located at 1202 Williamson St., Suite B, Madison, Wisconsin. During the Class Period, Plaintiff’s members purchased prescription pharmaceuticals manufactured and/or distributed by the Defendant Drug Manufacturers and made inflated payments or co-payments based in whole or in part upon the published AWP, and were injured by the illegal conduct alleged herein. For example, Ms. Ida Johnson of Oconomowoc, Wisconsin, and active WCA member, purchased Pfizer’s drug Lipitor in whole or in part based upon Defendants’ published AWP. As an unincorporated association, WCA has standing to pursue this action under Fed. R. Civ. P. 17(b)(1). WCA appears in this action for purposes of seeking declaratory, injunctive and other

non-monetary relief pursuant to 28 U.S.C. §§ 2201, 2202, §16 of the Clayton Act and any other applicable statute.

34. Plaintiff New York StateWide Senior Action Council (“StateWide”) is a grassroots membership organization made up of individual senior citizens and senior citizen clubs from all parts of New York State. It is located at 275 State Street, Albany, New York. During the Class Period, StateWide’s members purchased prescription pharmaceuticals manufactured and/or distributed by the Defendant Drug Manufacturers, made inflated payments or co-payments based in whole or in part upon published AWPs, and were injured by the illegal conduct alleged herein. For example, Ms. Mary Jane Snyder of Clifton Park, New York, an active StateWide member, purchased AstraZenaca’s drugs Prilosec and Nexium, Boehringer’s drug Atrovent, BMS’s drug Tequin, Novartis’ drug Starlix and Schering’s drugs Clarinex and K-Dur based in whole or in part on Defendants’ published AWPs. As an unincorporated association, StateWide has standing to pursue this action under Fed. R. Civ. P. 17(b)(1). StateWide appears in this action for purposes of seeking declaratory, injunctive and other non-monetary relief pursuant to 28 U.S.C. §§ 2201, 2202, §16 of the Clayton Act and any other applicable statute.

35. Plaintiff Citizen Action of New York (“CANY”) is a coalition of labor, senior citizen, women’s, student, tenant and community organizations that works with community activists for social and economic justice. It is located at 94 Central Avenue, Albany, New York. During the Class Period, CANY’s members purchased prescription pharmaceuticals manufactured and/or distributed by the Defendant Drug Manufacturers, made inflated payments or co-payments therefore based in whole or in part on published AWPs, and were injured by the illegal conduct alleged herein. For example, Ms. Marilyn Gourley of Binghamton, New York, an active CANY member, purchased Pfizer’s drug Zoloft based in whole or in part upon Defendants’ published AWPs. As an unincorporated association, CANY has standing to pursue

this action under Fed. R. Civ. P. 17(b)(1). CANY appears in this action for purposes of seeking declaratory, injunctive and other non-monetary relief pursuant to 28 U.S.C. §§ 2201, 2202, § 16 of the Clayton Act and any other applicable statute.

36. Plaintiff Citizens for Consumer Justice (“CCJ”) is a Pennsylvania nonprofit umbrella organization that promotes affordable, quality health care. It is located at Architects Building, 117 South 17th Street, Suite 311, Philadelphia, Pennsylvania. During the Class Period, CCJ’s members purchased prescription pharmaceuticals manufactured and/or distributed by the Defendant Drug Manufacturers, made inflated payments or copayments based in whole or in part on published AWPs, and were injured by the illegal conduct alleged herein. For example, Ms. Patricia Pudyk of Aliquippa, Pennsylvania, an active CCJ member, purchased AZ’s drug Nexium in whole or in part based upon Defendants’ published AWP. As an unincorporated association, CCJ has standing to pursue this action under Fed. R. Civ. P. 17(b)(1). CCJ appears in this action for purposes of seeking declaratory, injunctive and other non-monetary relief pursuant to 28 U.S.C. §§ 2201, 2202, § 16 of the Clayton Act and any other applicable statute.

36(a). As set forth above, each of the plaintiffs has paid for drugs at prices that are expressly tied to AWP. Each has overpaid for AWPs by virtue of defendants’ manipulation of the AWPs for these drugs.

B. Defendants

37. The acts charged in this Complaint as having been done by the Defendants were authorized, ordered, or done by their officers, agents, employees, or representatives while actively engaged in the management of the Defendants’ business or affairs.

38. Various other individuals, partnerships, sole proprietors, business entities, companies and corporations, presently unknown to Plaintiffs and not named as Defendants in this Complaint, participated as co-conspirators in the violations alleged in this Complaint and performed acts and made statements in furtherance thereof. Such unknown persons or entities

acted as co-conspirators and aided, abetted or participated with Defendants in the commission of the wrongful acts alleged in this Complaint.

1. Abbott

39. Defendant Abbott Laboratories (“Abbott”) is an Illinois corporation with its principal place of business at 100 Abbott Park Road, Abbott Park, Illinois. Abbott is a diversified health care company that discovers, develops, manufactures, and markets health care products and pharmaceuticals. Abbott’s principal businesses are global pharmaceuticals, nutritionals, and medical products. Abbott reported revenues for the year 2000 of approximately \$13.7 billion and net earnings of \$2.8 billion.

40. Abbott, one of the world’s largest pharmaceutical companies, is in the business of manufacturing prescription medications for clinical distribution by Medicare Plan B providers nationwide. The drugs manufactured by Abbott and covered by Medicare Part B include, but may not be limited to: acetylcysteine, acyclovir, amikacin sulfate, calcitriol, cimetidine hydrochloride, clindamycin phosphate, dextrose, dextrose sodium chloride, diazepam, furosemide, gentamicin sulfate, heparin lock flush, metholprednisolone sodium succinate, sodium chloride, tobramycin sulfate, vancomycin, and zemplar.

41. Abbott is also sued herein in its capacity as a participant in the Together Rx conspiracy.

2. Amgen

42. Defendant Amgen Inc. (“Amgen”) is a Delaware corporation with its principal place of business at One Amgen Drive, Thousand Oaks, California. Amgen is a biotechnology corporation that focuses its research and development efforts on drugs related to nephrology, cancer, inflammation, neurology and metabolism. In 2000, Amgen’s revenues exceeded \$3.6 billion.

43. Amgen is in the business of manufacturing and distributing prescription pharmaceuticals for distribution by Medicare Plan B providers nationwide. Pharmaceuticals that are manufactured by Amgen and covered by Medicare Part B include, but may not be limited to: Epogen® (epoetin alfa) and Neupogen® (filgrastim).

3. AstraZeneca

44. Defendant Zeneca, Inc. ("Zeneca") is a Delaware corporation with its principal place of business at Malvern, Pennsylvania. Zeneca is a wholly owned subsidiary of AstraZeneca, PLC, a limited liability company domiciled in the United Kingdom.

45. Defendant AstraZeneca US is a Delaware corporation with its principal place of business at 1800 Concord Pike, Wilmington, Delaware.

46. Defendant AstraZeneca Pharmaceuticals L.P. is a Delaware corporation, with its principal place of business located at 1800 Concord Pike, Wilmington, Delaware. AstraZeneca Pharmaceuticals L.P. is owned and controlled by AstraZeneca PLC, a public limited liability company domiciled in the United Kingdom.

47. AstraZeneca, PLC, Zeneca, Inc., AstraZeneca Pharmaceuticals L.P. and AstraZeneca U.S. are collectively referred to as "AstraZeneca."

48. AstraZeneca maintains research and development and manufacturing facilities worldwide, including in the United States. AstraZeneca reported annual sales of \$16.5 billion in 2001, with an operating profit of \$4.2 billion.

49. AstraZeneca manufactures and markets several drugs covered by Medicare Part B including, but not limited to: Zoladex® (goserelin acetate implant), Nolvadex® (tamoxifen citrate), Tomudex® (raltitrexed), and Diprivan® (propofol).

50. AstraZeneca is also sued herein in its capacity as a participant in the Together Rx conspiracy.

4. The Aventis Group (Aventis, Pharma, Hoechst and Behring)

51. Defendant Aventis Pharmaceuticals, Inc. ("Pharma") is a Delaware corporation with its principal place of business located at 300-400 Somerset Corporate Blvd., Bridgewater, New Jersey. Pharma is a wholly owned subsidiary of Aventis, S.A., a company domiciled in France. Pharma is comprised of the U.S. commercial operations of predecessor companies Rhone-Poulenc Rorer, S.A. and Defendant Hoechst Marion Roussel, Inc. ("Hoechst"). Prior to its acquisition by Pharma, Hoechst was a Delaware corporation with its principal place of business located at 10236 Marion Park Drive, Kansas City, Missouri.

52. Pharma's principal business activities are the discovery, development, manufacture and sale of prescription pharmaceuticals in the areas of cardiology, oncology, infectious diseases, arthritis, allergies and respiratory disorders, diabetes and central nervous system disorders. Pharma reported U.S. net sales of approximately \$5.8 billion in 2001.

53. Defendant Aventis Behring L.L.C. ("Behring"), located at 1020 First Avenue, King of Prussia, Pennsylvania, formerly did business as Centeon L.L.C., a 50/50 joint venture between Hoechst and Rhone-Poulenc Rorer, S.A. When Centeon L.L.C.'s parent companies merged to create Aventis in 1996, Behring became its wholly-owned subsidiary.

54. Behring is the plasma protein business of Pharma, producing a line of therapies including coagulation therapies for the treatment of hemophilia, wound healing agents used during major surgical procedures, inhibitor treatments that inhibit the formation of blood clots, immunoglobulins for the prevention and treatment of immune disorders, and plasma expanders for the treatment of a variety of conditions such as shock, burns and circulatory disorders. In 2000, Behring held assets estimated at \$1.5 billion.

55. The drugs manufactured by Pharma, Hoechst and Behring (collectively referred to as "The Aventis Group") and covered by Medicare Part B include, but may not be limited to:

Anzemet® (dolasteron mesylate), Bioclate® (antihemo factor viii), Gammar® (immune globulin), Helixate® (antihemo factor viii), Humate-P® (antihemo factor viii), Mononine® (antihemo factor ix complex), Monoclate-P® (antihemo factor viii), and Taxotere® (docetaxel).

56. Aventis is also sued in its capacity as a participant in the Together Card Rx conspiracy.

5. Baxter

57. Defendant Baxter International Inc. ("Baxter") is a Delaware corporation with its principal place of business at One Baxter Parkway, Deerfield, Illinois. Baxter manufactures and distributes prescription drugs to clinical administrators. Baxter's annual sales from January 1, 2000 through December 31, 2000 were over \$6.8 billion.

58. Defendant Baxter Healthcare Corporation is the principal domestic operating subsidiary of Baxter International. Baxter International and Baxter Healthcare Corporation are collectively referred to as "Baxter."

59. Baxter is a global medical products company that, *inter alia*, develops, manufactures, markets and/or distributes drugs to treat cancer, trauma, hemophilia, immune deficiencies, infectious diseases, kidney disease and other disorders. Baxter reported a year 2000 sales of \$6.9 billion.

60. The drugs developed, manufactured, marketed, sold and/or distributed by Baxter that are covered by Medicare Part B include, but may not be limited to: albumin, Bebulin® (factor ix complex), Buminat® (human albumin), dextrose, dextrose sodium chloride, Gammagard® (immune globulin), Iveegam® (immune globulin), Holoxan® (ifosfanide), Uromitexan® (mesna), Endoxan® (cyclophosphamide), Hemofil M® (antihemo factor viii), Proplex T® (factor ix complex), Recombinate® (antihemo factor viii), cisplatin, sodium chloride, and diazepam.

6. Bayer

61. Defendant Bayer Corporation (“Bayer”) is an Indiana corporation with its principal place of business located at 100 Bayer Road, Pittsburgh, Pennsylvania. Bayer is a wholly owned United States subsidiary of a German corporation, Bayer AG. Bayer’s pharmaceutical division is located at 400 Morgan Lane, West Haven, Connecticut.

62. Bayer is a highly diversified health care company whose principal business includes the development, manufacture, marketing, sale and/or distribution of healthcare products and services, including pharmaceuticals. Bayer reported sales in the United States of \$10.1 billion in 2001 and \$8.9 billion in 1999.

63. Bayer is in the business of manufacturing and distributing prescription pharmaceuticals for distribution by Medicare Plan B providers nationwide. The pharmaceutical drugs manufactured by Bayer and covered by Medicare Part B include, but may not be limited to: Kogenate® (antihemo factor viii), FS/Kogenate® (antihemo factor viii), and Koate-DVI® (antihemo factor viii) and Gamimune® (immune globulin), all used to treat hemophilia, and Gamimune® which is used in the treatment of immunodeficiency and autoimmune disorders.

7. The Boehringer Group (Boehringer, Ben Venue, Bedford)

64. Defendant Boehringer Ingelheim Corp. (“Boehringer”) is a Nevada corporation with its principal place of business located at 900 Ridgefield Road, Ridgefield, Connecticut. Boehringer is a United States subsidiary of Pharma Investment Ltd., of Burlington, Canada, which in turn is a division of C.H. Boehringer Sohn Gurdstucksverwaltung GmbH & Co. KG of Ingelheim, Germany. Boehringer designs, manufactures and markets pharmaceuticals. Boehringer is in the business of manufacturing and distributing prescription pharmaceuticals for distribution by Medicare Plan B providers nationwide.

65. Defendant Ben Venue Laboratories Inc. (“Ben Venue”) is a Delaware corporation with its principal place of business located at 300 Northfield Road, Bedford, Ohio. Ben Venue is a wholly owned subsidiary of Defendant Boehringer. Ben Venue is in the business of

manufacturing and distributing prescription pharmaceuticals for distribution by Medicare Plan B providers nationwide.

66. Defendant Bedford Laboratories (“Bedford”) is a division of Ben Venue with its principal place of business located at 300 Northfield Road, Bedford, Ohio. Bedford manufactures and markets injectable pharmaceuticals. Bedford is in the business of manufacturing and distributing prescription pharmaceuticals for distribution by Medicare Plan B providers nationwide. (Boehringer, Ben Venue, and Bedford are collectively referred to herein as the “Boehringer Group.”)

67. The pharmaceuticals manufactured by the Boehringer Group and covered by Medicare Part B include, but may not be limited to injectable forms of: acyclovir, bleomycin, cisplatin, cyclosporine, cytarabine, doxorubicin hydrochloride, doxorubicin hydrochloride, doxycycline, etoposide, leucovorin calcium, leucovorin calcium, methotrexate, mitomycin, paclitaxel, pamidronate disodium, and vinblastine sulfate.

8. Braun

68. Defendant B. Braun of America, Inc. is a Pennsylvania corporation with its principal place of business located at 824 Twelfth Avenue, Bethlehem, Pennsylvania. B. Braun of America is a wholly-owned subsidiary of B. Braun Melsunger Aktiengesellschaft.

69. In 1997, B. Braun of America acquired McGaw, Inc. (“McGaw”), a Delaware corporation with a principal place of business in Irvine, California. B. Braun McGaw (“Braun”), which produces pharmaceutical products, is a wholly-owned subsidiary of B. Braun of America, Inc. Upon information and belief, McGaw ceased to maintain a separate corporate entity upon the acquisition of McGaw by B. Braun of America. Until its acquisition by B. Braun of America, McGaw was in the business of manufacturing and distributing prescription pharmaceuticals for distribution by Medicare Plan B providers nationwide. (B. Braun of America, McGaw and B. Braun McGaw are collectively referred to herein as “Braun.”) Braun

designs, manufactures and markets medical devices and certain intravenous solutions. Braun is in the business of manufacturing and distributing prescription pharmaceuticals for distribution by Medicare Plan B providers nationwide.

70. The pharmaceuticals manufactured by Braun and covered by Medicare Part B include, but may not be limited to intravenous solutions of dextrose, dextrose sodium chloride, and sodium chloride.

9. The BMS Group (Oncology Therapeutics; Apothecon)

71. Defendant Bristol-Myers Squibb Co. ("Bristol-Myers") is a Delaware corporation with its principal place of business located at 345 Park Avenue, New York, New York. Bristol-Myers is a multi-national health care company specializing in the manufacturing, marketing and sale of pharmaceuticals and medical devices. For the year 2000, Bristol-Meyers reported revenues of approximately \$20 billion and net earnings of \$4.7 billion.

72. Defendant Oncology Therapeutics Network Corp. ("OTN") is a Delaware corporation with its principal place of business located at 395 Oyster Point Boulevard, Suite 405, South San Francisco, California. OTN has been a wholly-owned subsidiary of Bristol-Myers since its acquisition in 1996. Prior to 1996, OTN was an independent company. In 2001, OTN reported revenues of over \$1.4 billion.

73. OTN is a healthcare services and distribution firm that directly sells Bristol-Myers' infusion oncology drugs and related products to approximately 2,300 office-based oncology practices in the United States. At the time of its acquisition by Bristol-Myers, OTN was the leading distributor of chemotherapeutic drugs and related products for the treatment of cancer. Bristol-Myers paid OTN a commission for marketing and selling its drugs. Both prior to and after Bristol-Myers acquired OTN, Bristol-Myers marketed and sold its drugs directly to medical providers across the country, and thus Bristol-Myers and OTN employed and maintained extensive marketing and sales departments.

74. Defendant Apothecon, Inc. ("Apothecon") is a Delaware corporation with its principal place of business located in Princeton, New Jersey. It is a subsidiary of Bristol-Myers specializing in small to mid-size niche brand and generic products.

75. Bristol-Myers, OTN and Apothecon are collectively referred to herein as the "BMS Group."

76. The BMS Group manufactures and distributes prescription drugs that are clinically distributed by Medicare Plan B providers nationwide. The drugs manufactured by the BMS Group and covered by Medicare Part B include, but may not be limited to: Blenoxane® (bleomycin sulfate), Paraplatin® (carboplatin), Cytoxan® (cyclophosphamide), Rubex® (doxorubicin hydrochloride), Etopophos® (etoposide), Vepesid® (etoposide), TaxolV (paclitaxel), and Fungizone® (amphotericin B).

77. Bristol-Myers is also sued herein in its capacity as a participant in the Together Rx conspiracy.

78. The BMS Group engages in an organization-wide and deliberate scheme to inflate AWPs. The BMS Group has stated fraudulent AWPs for all or almost all of its drugs including Amikacin Sulfate, Amphotericin B, Bleomycin Sulfate, Cyclophosphamide, Vespid (Etoposide), Carboplatin (Paraplatin), Taxol (paclitaxel), and Blenoxane. The specific drugs of the BMS Group for which relief is sought in this case are set forth in Appendix A.

10. Dey, Inc.

79. Defendant Dey, Inc. ("Dey") is a Delaware corporation with its principal place of business at 2751 Napa Valley Corporate Drive, Napa, California. Dey is a unit of Merck KGaA, a German pharmaceutical conglomerate.

80. Dey is a specialty pharmaceutical company that primarily develops, manufactures and markets generic drugs used in the treatment of selected respiratory diseases and allergies.

Dey, one of the largest U.S. manufacturers of such pharmaceuticals, had net sales of \$266 million in 1998.

81. The drugs manufactured by Dey and covered by Medicare Part B include, but may not be limited to: albuterol sulfate, acetylcysteine, cromolyn sodium, ipratropium bromide, and metaproterenol sulfate.

82. Defendant Dey, Inc. f/k/a Dey Laboratories, Inc. ("Dey") is a corporation organized under the laws of Delaware with its principal offices in Napa, California.

83. Dey is a specialty pharmaceutical company focusing on drug products for respiratory diseases and related allergies. The products it manufactures and publishes AWPs on include: Ipratropium, Bromide; Metaproterenol Sulfate, and Accuneb.

11. The Fujisawa Group (Fujisawa Healthcare, Fujisawa USA)

84. Defendant Fujisawa Healthcare, Inc. ("Fujisawa Healthcare") is a Delaware corporation with its principal place of business located at Three Parkway North, Deerfield, Illinois, 60015. Fujisawa Healthcare is a wholly-owned subsidiary of Fujisawa Pharmaceutical Co. Ltd., a Japanese corporation. Fujisawa Healthcare focuses its efforts in the therapeutic areas of immuno-suppression and transplantation, cardiovascular care, skin care, oncology, and antifungal and anti-infective treatment.

85. Defendant Fujisawa USA, Inc. ("Fujisawa USA") is a Delaware corporation with its principal place of business located at Three Parkway North, Deerfield, Illinois. Fujisawa USA was a wholly-owned subsidiary of Fujisawa Pharmaceutical Co. Ltd. In 1998, Fujisawa Healthcare assumed responsibility for Fujisawa USA's portfolio of proprietary products

86. The drugs manufactured by Fujisawa Healthcare and Fujisawa USA (collectively referred to as "The Fujisawa Group") and covered by Medicare Part B include, but may not be limited to: Acyclovir Sodium, Dexamethasone Sodium Phosphate, Doxorubicin Hydrochloride, Fluorouracil, Gentamicin Sulfate, Pentamidine Isethionate, and Vancomycin Hydrochloride.

12. The GSK Group (GlaxoSmithKline, SmithKline Beecham, Glaxo Wellcome)

87. Defendant GlaxoSmithKline, P.L.C. ("GlaxoSmithKline") is a public limited company incorporated under the laws of England and Wales, with its corporate headquarters located at 980 Great West Road, Brentford, Middlesex, United Kingdom TW8 9GS. GlaxoSmithKline was created through the December 27, 2000, merger of GlaxoWellcome, P.L.C. and SmithKline Beecham, P.L.C. GlaxoSmithKline's operational headquarters are located at One Franklin Plaza, 16th and Race Streets, Philadelphia, Pennsylvania.

88. Defendant SmithKline Beecham Corporation ("SKB"), a wholly-owned U.S. subsidiary of the former SmithKline Beecham P.L.C., is a Pennsylvania corporation with its principal place of business at One Franklin Plaza, 16th and Race Streets, Philadelphia, Pennsylvania.

89. Defendant GlaxoWellcome, Inc. ("Glaxo"), a wholly-owned subsidiary of GlaxoSmithKline, is a North Carolina corporation with its principal place of business at 5 Moore Drive, P.O. Box 13398, Research Triangle Park, North Carolina. Cerenex Pharmaceuticals ("Cerenex"), a division of Glaxo prior to the merger, was responsible for Glaxo's central nervous system drugs, including Zofran.

90. Defendants GlaxoSmithKline, SKB and Glaxo are referred to collectively as the "GSK Group."

91. The GSK Group is a diversified pharmaceutical company which controls an estimated 7 percent of the world's pharmaceutical market. In 2001, the GSK Group reported pharmaceutical sales of \$24.8 billion.

92. The drugs manufactured by the GSK Group and covered by Medicare Part B include, but may not be limited to: Hycamtin® (topotecan hydrochloride), Ventolin® (albuterol) and Zofran® (ondansetron hydrochloride). Pierre Fabré Médicament licenses another Medicare Part B drug, Navelbine® (vinorelbine tartrate), to the GSK Group. SmithKline Beecham P.L.C. manufactured and sold Kytril® (granisteron hydrochloride), another drug covered by Medicare

Part B (and a competitor to Zofran®), prior to the merger. To secure regulatory approval for the merger, SmithKline Beecham P.L.C. sold Kytril®'s global rights to the Roche Group in December of 2000.

93. GSK is also sued herein as a member of the Together Rx conspiracy.

13. Hoffman-LaRoche, Inc.

94. Defendant Hoffman-LaRoche, Inc. ("Roche") is a New Jersey corporation with its principal place of business at 340 Kingsland Street, Nutley, New Jersey. Roche is a research-based company that develops, manufactures and markets numerous prescription and non-prescription drugs.

95. Roche is in the business of manufacturing and distributing prescription pharmaceuticals for distribution by Medicare Plan B providers nationwide. Pharmaceuticals that are manufactured by Roche and covered by Medicare Part B include, but may not be limited to: Cellcept® (mycophenolate mofetil), Cytovene® (ganciclovir), Demadex® (torsemide), Kytril® (gransetron HCL), Rolcatrol® (calcitriol), Rocephin® (ceftriaxone), Roferon-A® (Interferon 2-alfa), Toradol® (ketorolac tromethamine), Valium® (diazepam), Versed® (midazolam), Xeloda® (capecitabine), Zenapx® (daclizumab), Rituxan® (rituximab), Herceptin® (trastuzumab), and Xeloda® (capecitabine).

96. In addition to manufacturing and marketing drugs that are reimbursed by Medicare Plan B, Roche also manufactures and distributes other named brand drugs for which it publishes, or causes to be published, an AWP in various industry compendia.

14. Immunex

97. Defendant Immunex Corporation ("Immunex"), a wholly owned subsidiary of Defendant Amgen, Inc., is a Washington corporation with its principal place of business at 51 University Street, Seattle, Washington. Immunex is a company that develops products for the

treatment of cancer, asthma, rheumatoid arthritis, inflammatory diseases, infectious diseases, and cardiovascular diseases. In 1999, its total revenues were \$542 million.

98. Immunex is in the business of manufacturing and distributing prescription pharmaceuticals for distribution by Medicare Plan B providers nationwide. Pharmaceutical drugs that are manufactured by Immunex and covered by Medicare Part B include, but may not be limited to: Leucovorin Calcium, Enbrel® (etanercept), Novantrone® (mitoxane hydrochloride), Leukine® (sargramostim), and Thioplex®(thiotepa).

99. Defendant Immunex has been a wholly owned subsidiary of Defendant Amgen, since Immunex' acquisition in July 2002.

15. The Johnson & Johnson Group (J&J, Centocor, Janssen, NcNeil, Ortho)

100. Defendant Johnson & Johnson ("J&J") is a New Jersey corporation with its principal place of business located at One Johnson & Johnson Plaza, New Brunswick, New Jersey. In 2001, pharmaceutical sales represented 45% of J&J's worldwide sales and 19% of its operational growth. J&J is in the business of manufacturing and distributing prescription pharmaceuticals for distribution by Medicare Plan B providers nationwide.

101. Defendant Centocor, Inc. ("Centocor") is a Pennsylvania corporation and has been a wholly owned subsidiary of Defendant J&J since its acquisition by J&J in October 1999. Centocor's principal place of business is located at 200 Great Valley Parkway, Malvern, Pennsylvania. Centocor manufactures, markets and distributes prescription pharmaceuticals for distribution by Medicare Plan B providers nationwide.

102. Defendant Janssen Pharmaceutica Products, L.P. ("Janssen") is a New Jersey limited partnership with a principal place of business located at 1125 Trenton-Harbourton Road, Titusville, New Jersey 08560. Janssen is a subsidiary of Johnson & Johnson. Janssen is sued for its role in the Together Rx conspiracy.

103. Defendant McNeil-PPC, Inc., is a New Jersey corporation. McNeil-PPC, Inc. is a subsidiary of Johnson & Johnson. McNeil Consumer & Specialty Pharmaceuticals is a division of McNeil-PPC, Inc. and has a principal place of business located at 7050 Camp Hill Road, Fort Washington, Pennsylvania 19034. McNeil-PPC is sued for its role in the Together Rx conspiracy.

104. Defendant Ortho Biotech (“Ortho”) is New Jersey corporation and has been a wholly owned subsidiary of Defendant J&J since its formation by J&J in 1990. Ortho’s principal place of business is located at 700 U.S. Highway 202, Raritan, New Jersey. Ortho manufactures and distributes prescription pharmaceuticals for distribution by Medicare Plan B providers nationwide.

105. The drugs manufactured by J&J, Centocor, Ortho, McNeil-PPC and Janssen (collectively referred to as “J&J Group”) and covered by Medicare Part B include, but may not be limited to: ReoPro® (abciximab), an anti-blood clotting medication, Retavase® (reteplase), an anti blood clotting agent, Procrit® (epoetin alfa), for the treatment of anemia, Leustatin® (cladribine), for the treatment of leukemia, Orthoclone® (muromonab-CD3), used to prevent organ transplant rejection, Sporanox® (itraconazole), used in the treatment of fungal infections, and Remicade® (infliximab), an anti-inflammatory drug.

106. J&J, Ortho, McNeil and Janssen are also sued herein as members of the Together Rx conspiracy.

16. Novartis

107. Defendant Novartis Pharmaceuticals Corporation (“Novartis”) is a New Jersey corporation with its principal place of business at One Health Plaza, East Hanover, New Jersey. Novartis, a U.S. affiliate of Swiss-based Novartis AG, has core businesses in pharmaceuticals, consumer health, generics, eye care and animal health. Novartis AG reported a net income of \$4.2 billion on sales of \$19.1 billion in 2001.

108. The drugs manufactured by Novartis and distributed through the Together Rx Card Program include, but may not be limited to: Clozaril, CombiPatch, Comtan, Diovan, Diovan HCT, Elidel, Estraderm, Exelon, Famvir, Femara, Focalin, Lamisil, Lescol/Lescol XL, Lotensin, Lotensin HCT, Miacalcin Injection & Nasal Spray, Parlodel, Rescula, Ritalin Hydrochloride, Ritalin LA, Starlix, Tegretol, Tegretol-XR, Trileptal, Vivelle/Vivelle-Dot, Voltaren Ophthalmic, Zaditor, and Zelnorm.

17. Pfizer, Inc.

109. Defendant Pfizer, Inc. ("Pfizer") is a Delaware corporation with its principal place of business at 235 East 42nd Street, New York, New York. Pfizer is one of the largest pharmaceutical companies in the United States, whether measured by number of prescriptions written, revenues, or market capitalization.

110. Pfizer is in the business of manufacturing and distributing prescription pharmaceuticals for distribution by Medicare Plan B providers nationwide. Pharmaceuticals that are manufactured by the Pfizer Group and covered by Medicare Part B include, but may not be limited to: Cerebyx® (fosphenytoin sodium injection), Dilatin® (phenytoin), Diflucan® (fluconazole), Zithromax® (azithromycin), Trovan® (trovafloxacin mesylate), and Unasyn® (ampicillin sodium/sulbactam sodium).

111. In addition to manufacturing and marketing drugs that are reimbursed by Medicare Plan B, the Pfizer Group also manufactures and distributes other named brand drugs for which it publishes, or causes to be published, an AWP in various industry compendia.

18. The Pharmacia Group (Pharmacia and Upjohn)

112. Defendant Pharmacia Corporation ("Pharmacia") is a Delaware corporation with its principal place of business located at 100 Route 206, North Peapack, New Jersey. Pharmacia was created through the merger of Defendant Pharmacia and Upjohn, Inc. and Monsanto Company on March 31, 2000.

113. Defendant Pharmacia & Upjohn, Inc. ("P&U") is a subsidiary of Pharmacia Corp. In 1995, P&U was formed through the merger of Pharmacia AB and The Upjohn Company. P&U became a global provider of human healthcare products, animal health products, diagnostics and specialty products. In 1998, Pharmacia & Upjohn relocated its global headquarters from the United Kingdom to New Jersey. In September 1999, the company established its global headquarters on a 70-acre campus in Peapack, New Jersey. This site is now the management and pharmaceutical headquarters for Pharmacia.

114. Pharmacia is a highly diversified health care company whose business focuses on the discovery, development, manufacture and sale of a broad and diversified line of health care products and services, including pharmaceuticals, diagnostics and hospital products. Pharmacia's Prescription Pharmaceuticals business segment is involved in researching, developing, registering, manufacturing and selling prescription pharmaceutical products, including general therapeutics, ophthalmology, and hospital products, which include oncology products and diversified therapeutics. Pharmacia reported sales of \$18.1 billion for the fiscal year ended December 31, 2000. Pharmacia also reported \$12.0 billion in prescription pharmaceuticals sales for the year 2001, and \$10.8 billion in prescription pharmaceuticals sales for the year 2000. Prescription pharmaceuticals sales account for over 85 percent of Pharmacia's overall pharmaceutical sales. According to its Annual Report, Pharmacia's oncology drugs generated more than \$1 billion in sales in 2001.

115. The drugs manufactured by Pharmacia and P&U (collectively referred to as "The Pharmacia Group") and covered by Medicare Part B include, but may not be limited to: Adriamycin PFS® (doxorubicin hydrochloride), Adrucil® (fluorouracil), Amphocin® (amphotericin), Aromasin® (bleomycin), Camptosar® (irinotecan hydrochloride), Cleocin Phosphate® (clindamycin phosphate), Neosar ® (cyclophosphamide), Cytosar-U (cytarabine), Depo-Testosterone® (testosterone cypionate), Adriamycin PFS® (doxorubicin HCL), Ellence®

(epirubicin HCL), Toposar® (etoposide), Adrucil® (fluorouracil), Solu-Cortef® (hydrocortisone sodium succinate), Idamycin® (idarubicin hydrochloride), Medrol® (methylprednisolone), and Vincasar® (vincristine sulfate).

19. The Schering-Plough Group (Schering Plough & Warrick)

116. Defendant Schering-Plough Corporation (“Schering-Plough”) is a New Jersey corporation with its principal place of business located at 2000 Galloping Hill Road, Kenilworth, New Jersey.

117. Schering-Plough’s primary business involves prescription products in core product categories, including allergy and respiratory, anti-infective and anticancer, cardiovasculars, dermatologicals and central nervous systems and other disorders. Schering-Plough’s revenues in 2001 totaled \$9.8 billion.

118. Defendant Warrick Pharmaceuticals Corporation (“Warrick”), is a Delaware corporation with its principal place of business at 12125 Moya Boulevard, Reno, Nevada. Warrick is a wholly-owned subsidiary of Defendant Schering-Plough and has been since its formation in 1993. Warrick manufactures generic pharmaceuticals.

119. The drugs manufactured by Schering-Plough and Warrick (collectively at times referred to as “The Schering-Plough Group”) and covered by Medicare Part B include, but may not be limited to: Proventil® (albuterol sulfate), Integrelin® (eptifibatide), Intron A® (interferon alfa-2b recombinant), and Temodar® (temozolomide). The Schering-Plough Group’s Albuterol sulfate sales alone totaled \$154 million in 2000.

20. The Sicor Group (Sicor and Gensia)

120. Defendant Sicor, Inc. (“Sicor”) is a Delaware corporation with its principal place of business located at 19 Hughes, Irvine, California. Sicor was the result of the 1997 merger between Defendant Gensia, Inc. (“Gensia”), a finished dosage manufacturer, and Rakepoll Holding, a Europe-based supplier of active pharmaceutical ingredients.

121. Sicor markets itself as a vertically-integrated specialty pharmaceutical company with expertise in the development, manufacturing and marketing of injectable pharmaceutical products, primarily used worldwide by hospitals. Sicor's finished dosage products manufacturing operations account for 32% of its total revenue, and is comprised of a portfolio of products that includes oncology, anesthesiology, and critical care. Sicor's 2001 revenues totaled nearly \$370 million. According to its website, Sicor operates its business through several subsidiaries.

122. Defendant Gensia Sicor Pharmaceuticals, Inc. ("Gensia Sicor"), a Delaware corporation, is a wholly-owned subsidiary of Sicor with its principal place of business located at 17 Hughes, Irvine, California. Gensia Sicor focuses on acute-care multisource products in the fields of oncology, cardiology, and anesthesiology. Gensia Sicor's injectable drug business includes more than 60 products.

123. In 1999, Gensia Sicor entered into a sales distribution agreement with Abbott Laboratories under which the two companies formed a strategic alliance for the marketing and distribution of oncology products in the U.S. The agreement was restructured in March 2002. In 1999, Gensia Sicor also amended an earlier agreement with Baxter Pharmaceutical Products, Inc. Notably, Abbott (6%) and Baxter (34%) accounted for nearly 40% of Sicor's total product sales in 2001.

124. The drugs manufactured by Sicor, Gensia, and Gensia Sicor (collectively referred to as "The Sicor Group") and covered by Medicare Part B include, but may not be limited to: amikacin sulfate and tobramycin sulfate.

21. TAP

125. Defendant TAP Pharmaceutical Products, Inc. ("TAP") is a corporation that arose in 1977 from a partnership between Takeda Chemical Industries, Ltd. and Defendant Abbott,

under which each company owns 50 percent of TAP's stock. Abbott and Takeda jointly control TAP's operations and rotate control of TAP's presidency.

126. Prior to April 2000, TAP was known as TAP Holdings, Inc. TAP, together with its subsidiary, TAP Pharmaceuticals, Inc., develops and markets pharmaceutical products for the United States and Canada. TAP's headquarters is located in Waukegan, Illinois.

127. The pharmaceuticals manufactured by TAP include Lupron and Prevacid.

128. TAP is also sued herein for its role in the Together Rx Card Program.

22. Watson

129. Defendant Watson Pharmaceuticals, Inc. ("Watson") is a Delaware corporation with its principal place of business at 311 Bonnie Circle, Corona, California. Watson develops, manufactures and markets brand and generic pharmaceuticals. Watson is in the business of manufacturing and distributing prescription pharmaceuticals for distribution by Medicare Plan B providers nationwide.

130. The pharmaceuticals manufactured by Watson and covered by Medicare Part B include, but may not be limited to: albuterol sulfate, dexamethasone acetate, diazepam, gentamicin sulfate, iron dextran, testosterone enanthate, vancomycin hydrochloride, and cytarabine.

23. Together Rx

131. Defendant Together Rx LLC is a Delaware limited liability company, formed and controlled by its founding partners: Abbott; AstraZeneca; Aventis; Bristol; GSK, Janssen; Novartis; and Ortho-McNeil, and later TAP.

**IV. GENERAL ALLEGATIONS APPLICABLE
TO ALL DEFENDANTS**

132. The allegations contained herein apply generally to all Defendants.

A. The AWP System

133. There are approximately 65,000 different drug products in the United States market, including different dosages of the same drug. Prescription drugs are dispensed to patients by or through different types of medical providers, including but not limited to: (a) physicians who administer the drug in an office, (b) retail pharmacies, (c) home infusion pharmacies, and (d) other medical providers.

134. Providers regularly submit claims for reimbursement, seeking payment for the drugs from Medicare, insurers and patients. During the Class Period, the Defendants were aware that the Medicare program and virtually all end payors (the latter are included as members of the Class) use published AWPs to reimburse providers for drugs. Use of the published AWPs to establish reimbursement rates for drugs is an industry-wide practice and exists with respect to all classes of drugs, brand name and generic and is used for Part B drugs and non-Part B drugs.

135. There are several pharmaceutical industry compendia that periodically publish, in printed and electronic media, the AWPs for the tens of thousands of drugs on the market, including the *Drug Topics Red Book* (the “*Red Book*”), *American Druggist First Databank Annual Director of Pharmaceuticals* and *Essential Director of Pharmaceuticals* (the “*Blue Book*”) and Medi-Span’s *Master Drug Database* (collectively referred to herein as the “Publishers”). These Publishers publish AWPs for the various dosage forms for drugs. And the AWPs are published for Part B, non-Part B, brand name and generic drugs.

136. In periodically announcing the AWP for each drug, during the time period relevant to this Complaint the Publishers publish the prices that are supplied to them by the Defendant Drug Manufacturers for their respective drugs. For instance, the forward to the 1999 edition of the *Red Book* states that “all pricing information is supplied and verified by the products’ manufacturers, and it should be noted that no independent review of those prices for accuracy is conducted.” In addition, a June 1996 Dow Jones news article reported that Phil Southerd, an associate product manager of the *Red Book*, stated that it only publishes prices that

are faxed directly from the manufacturer. Thus, the Defendant Drug Manufacturers control the prices listed as the AWPs for each drug listed by the Publisher.

137. A system that bases its reimbursement rates for drugs on the published AWP is thus dependent on the honesty of the drug manufacturers. The Defendant Drug Manufacturers knew they could directly control and fabricate the AWP for their drugs at any time by forwarding to the Publishers a phony AWP. The Defendant Drug Manufacturers also knew that actual transaction price data – the amounts charged to providers and others for their drugs – was not publicly available, and they kept this information (on which AWPs should have been calculated) highly confidential and secret.

138. As detailed, the AWPs for the drugs at issue here bore little relationship to the drugs' pricing in the marketplace. They were simply fabricated and overstated in furtherance of Defendants' scheme to generate the profit spread to providers, PBMs and others and to increase Defendants' profits at the expense of Plaintiffs and the Class members.

139. Plaintiffs and the members of the Class paid for the drugs based on the inflated AWPs reported by the Defendant Drug Manufacturers.

140. The Defendant Drug Manufacturers' pattern of fraudulent conduct in artificially inflating the AWPs for their drugs (sometimes referred to herein as the "AWP Scheme") directly caused Plaintiffs and the members of the Class to substantially overpay for those drugs.

141. As detailed below, this overpayment manifested itself in two contexts, both of which were well known and understood by the Defendant Drug Manufacturers: (i) all drugs administered under Medicare Part B and (ii) drugs administered outside of the Medicare context whose reimbursement was established by use of AWP as a benchmark.

B. The Defendant Drug Manufacturers Commit AWP Fraud to Increase Market Share For Their Drugs Covered by Medicare Part B

1. The Medicare Insurance Program

142. In 1965, Congress enacted Title XVIII of the Social Security Act (“Medicare” or the “Medicare Program”) to pay for the cost of certain medical services and care.

143. The United States Department of Health & Human Services (“HHS”) is responsible for the funding, administration and supervision of the Medicare Program. The Centers for Medicare and Medicaid Services (“CMMS”), formerly known as the Health Care Financing Administration (“HCFA”), is a division of HHS and is directly responsible for the administration of the Medicare Program.

144. The Medicare Program generally does not cover the cost of prescription drugs that a Medicare beneficiary self administers (*e.g.*, by swallowing the drug in liquid or pill form). However, Medicare Part B does cover some drugs, including injectables administered directly by a doctor, certain oral anti-cancer drugs, and drugs furnished under a durable medical equipment benefit. Approximately 450 drugs are covered by Medicare Part B.

145. In determining the amount it will pay, Medicare calculates the “allowed” amount for the drug. During the period 1992 through 1997, Medicare’s reimbursement for Covered Drugs was set at the lesser of the estimated acquisition cost or national average wholesale price. For generic drugs (where more than one company sells a certain drug, sometimes called multiple-source drugs), payment was based on the lower of the estimated acquisition cost or the wholesale price that was defined as the median price for all sources of the generic form of the drug. This payment methodology was set forth in 42 C.F.R. § 405.517, a regulation first published in the Federal Register on November 25, 1991 and which became effective on or about January 1, 1992.

146. The estimated acquisition cost for a drug could be determined by the Medicare Program “based on surveys of the actual invoice prices paid for the drug” taking into

consideration the estimated acquisition cost, including “factors such as inventory, waste and spoilage.” However, historically it has been the AWP published in the *Red Book* or other compendia that has been used as a ceiling for Medicare reimbursement.

147. On January 1, 1998, 42 C.F.R. § 405.517 was amended to provide that the allowed amount would be based upon the lower of the billed charge on the Medicare claim form or 95 percent of AWP.

148. The Medicare Program has publicly announced that it would use the AWP published in pharmaceutical industry magazines as the basis for reimbursement. Specifically, Program Memorandum AB-99-63 (dated September 1999 but re-issuing PM AB-98-76 dated in December 1998), a publicly available Medicare Program bulletin, confirmed that reimbursement for certain Medicare Part B drugs and biologicals “are paid based on the lower of the billed charge or 95 percent of the AWP as reflected in sources such as the *Red Book*, *Blue Book*, or Medi-Span.”

149. Pursuant to PM AB-99-63, the AWP for a single-source drug or biological equals the AWP of the single product. For a multi-source drug or biological, the AWP is equal to the lesser of the median AWP of all of the generic forms of the drug or biological or the lowest brand name product AWP.

150. Medicare Part B reimburses medical providers 80% of the allowable amount for a drug. The remaining 20% is paid by the Medicare Part B beneficiary, and is called the “co-payment” amount. All medical providers are required by law to bill the 20% co-payment and make attempts beyond merely billing to collect that amount. In addition, beneficiaries under Part B are required to pay an annual deductible amount before Part B benefits are payable.

151. Some Medicare beneficiaries are able to purchase private Medigap insurance, which covers, among other things, all or part of the 20% co-payment for Covered Drugs.

152. In setting reimbursement rates, the Medicare Program uses the AWPs generated by the pharmaceutical industry. There are no regulations describing how AWPs are to be calculated, nor any regulatory process for approving them. Pharmaceutical companies do not report AWPs directly to the federal government, but instead send their pricing information to independent publishing companies that compile the data and publish the AWPs in trade publications, which are then used by the government, as well as private health plans.

153. The importance of an accurate AWP was recently reconfirmed by the Office of the Inspector General (“OIG”) in an April 2003 report: “Compliance Program Guidance for Pharmaceutical Manufacturers.” The OIG report found that the “government sets reimbursement with the expectation that the data provided are complete and accurate.” The OIG report made it clear that the AWP must be a meaningful figure that is not artificially inflated:

Where appropriate, manufacturers’ reported prices should accurately take into account price reductions, cash discounts, free goods contingent on a purchase agreement, rebates, up-front payments, coupons, goods in kind, free or reduced-price services, grants, or other price concessions or similar benefits offered to some or all purchasers. Any discount, price concession, or similar benefit offered on purchases of multiple products should be fairly apportioned among the products (and could potentially raise anti-kickback issues). Underlying assumptions used in connection with reported prices should be reasoned, consistent, and appropriately documented, and pharmaceutical manufacturers should retain all relevant records reflecting reported prices and efforts to comply with federal health care program requirements.

154. And, the OIG rejected the notion that purposeful AWP manipulation was a lawful practice:

The “spread” is the difference between the amount a customer pays for a product and the amount the customer receives upon resale of the product to the patient or other payer. In many situations under the federal programs, pharmaceutical manufacturers control not only the amount at which they sell a product to their customers, but also the amount those customers who purchase the product for their own accounts and thereafter bill the federal health care programs will be reimbursed. To the extent that a manufacturer controls the “spread,” it controls its customer’s profit.

Average Wholesale Price (AWP) is the benchmark often used to set reimbursement for prescription drugs under the Medicare Part B program. For covered drugs and biologicals, Medicare Part B generally reimburses at “95 percent of average wholesale price.” 42 U.S.C. 1395u(o). Similarly many state Medicaid programs and other payers base reimbursement for drugs and biologicals on AWP. Generally, AWP or pricing information used by commercial price reporting services to determine AWP is reported by pharmaceutical manufacturers.

If a pharmaceutical manufacturer purposefully manipulates the AWP to increase its customers’ profits by increasing the amount the federal health care programs reimburse its customers, the anti-kickback statute is implicated. Unlike *bona fide* discounts, which transfer remuneration from a seller to a buyer, manipulation of the AWP transfers remuneration to a seller’s immediate customer from a subsequent purchaser (the federal or state government). Under the anti-kickback statute, offering remuneration to a purchaser or referral source is improper if one purpose is to induce the purchase or referral of program business. In other words, it is illegal for a manufacturer knowingly to establish or inappropriately maintain a particular AWP if one purpose is to manipulate the “spread” to induce customers to purchase its product.

In the light of this risk, we recommend that manufacturers review their AWP reporting practices and methodology to confirm that marketing considerations do not influence the process.

Furthermore, manufacturers should review their marketing practices. *The conjunction of manipulation of the AWP to induce customers to purchase a product with active marketing of the spread is strong evidence of the unlawful intent necessary to trigger the anti-kickback statute.* Active marketing of the spread includes, for example, sales representatives promoting the spread as a reason to purchase the product or guaranteeing a certain profit or spread in exchange for the purchase of a product. [Emphasis added.]

1. Congressional and Other Federal Investigations and Actions

155. The United States Department of Justice (“DOJ”), the United States General Accounting Office (“GAO”), the Office of the Inspector General at the United States Department of HHS (“OIG”), and certain Congressional subcommittees have been investigating the Defendant Drug Manufacturers and other pharmaceutical manufacturers for questionable practices regarding the industry’s calculation of AWPs and for offering illegal incentives to providers.

156. In a letter dated September 28, 2000, sent from the House of Representatives Committee on Ways and Means, Subcommittee on Health to the President of the trade organization known as the Pharmaceutical Research and Manufacturers of America (most of the Defendant Drug Manufacturers are members of this association), Congressman Stark identified the improper scheme of manipulating AWPs and noted:

This corruptive scheme is perverting financial integrity of the Medicare program and harming beneficiaries who are required to pay 20% of Medicare's current limited drug benefit.

157. In his September 28 letter, Congressman Stark made the following five "shocking conclusions":

First – Certain drug manufacturers have abused their position of privilege in the United States by reporting falsely inflated drug prices in order to create a de facto improper kickback for their customers.

Second – Certain drug manufacturers have routinely acted with impunity in arranging improper financial inducements for their physicians and other healthcare provider customers.

Third – Certain drug manufacturers engage in the fraudulent price manipulation for the express purpose of causing federally funded health care programs to expend scarce tax dollars in order to arrange de facto kickbacks for the drug manufacturers' customers at a cost of billions of dollars.

Fourth – Certain drug manufacturers arrange kickbacks to improperly influence physicians' medical decisions and judgments notwithstanding the severely destructive effect upon the physician/patient relationship and the exercise of independent medical judgment.

Fifth – Certain drug manufacturers engage in illegal price manipulation in order to increase utilization of their drugs beyond that which is necessary and appropriate based on the exercise of independent medical judgment not affected by improper financial incentives.

158. The DOJ and Congressional investigations are ongoing.

2. Certain of the Defendants Drug Manufacturers' Fraudulent Conduct Within the Medicare Part B Program

159. As set forth below, certain of the Defendants Drug Manufacturers each perpetrated the alleged fraudulent scheme by using some and/or all of the following practices:

a. Artificially Inflating AWPs

160. Each Defendant Drug Manufacturer provided AWPs for each of its drugs to the *Red Book*, the *Blue Book*, Medi-Span and other pharmaceutical compendia for Covered Drugs and non-Part B drugs, both brand name and generic.

161. During the Class Period, the Defendant Drug Manufacturers deliberately and intentionally published AWPs for Covered Drugs that did not reflect the actual pricing structure of the drugs, but was created solely to cause Plaintiffs and the Class members to overpay for the Covered Drugs. The Defendant Drug Manufacturers created and perpetuated this scheme so that the medical providers who purchased these drugs at a low cost would bill patients and their insurers at the inflated AWPs and earn a substantial profit from the “spread” between the real cost and the various AWP-related reimbursement rates.

162. The Defendant Drug Manufacturers knew and understood that Medicare and Plaintiffs and the Class members used the *Red Book* and other publications to determine the AWPs of the drugs. Because the Defendant Drug Manufacturers controlled the AWPs published in the *Red Book* and other compendia, the Defendant Drug Manufacturers knew and understood that they could manipulate the providers’ profits from Plaintiffs and the Class. The purpose of artificially inflating the providers’ profits was to create an illegal kickback to the providers, funded by Plaintiffs’ and the Class members’ overpayments.

163. As part of their scheme, the Defendant Drug Manufacturers specifically instructed and expected the providers to charge the inflated AWPs for Covered Drugs to Medicare, Plaintiffs and the Class members.

b. Improper Use of Free Samples

164. The Defendant Drug Manufacturers, through their sales personnel and marketing representatives, also provided free samples of their drugs to providers as a means of lowering the price. The free samples were used to offset the total cost associated with the purchases of the drugs, thereby increasing the “spread.” Moreover, the Defendant Drug Manufacturers specifically told providers to bill Plaintiffs and the members of the Class for the free samples, which Defendants knew was unlawful.

165. Every free sample of a drug for which a provider bills a patient or insurer effectively reduces that provider’s overall cost for that drug. However, the full cost of the Covered Drug was charged to the Plaintiffs and the Class members, and the free sample is not used by the drug company in calculating the AWP, which in turn inflates the AWP.

166. Although the Defendant Drug Manufacturers provided free samples and marketed them as a way to lower the providers’ actual cost of the Covered Drugs, they did not include the value of the free samples in calculating the AWPs for those drugs. Thus, the Defendant Drug Manufacturers effectively and improperly passed on the cost of the free samples directly to Plaintiffs and the members of the Class.

c. Other Hidden and Improper Inducements and Price Reductions

167. The Defendant Drug Manufacturers also have provided and/or arranged for many other non-public financial inducements to stimulate sales of their Covered Drugs at the expense of Plaintiffs and the members of the Class. Such inducements included volume discounts, rebates, off-invoice pricing, free goods, credit memos, consulting fees, debt forgiveness and educational and promotional grants. All of these incentives were designed to lower the providers’ net cost of purchasing the Defendant Drug Manufacturers’ Covered Drugs. And again, the value of these services was kept “off the book,” so as to not be reflected in the AWP, which in turn inflates the AWP.

C. The Defendant Drug Manufacturers' Use of AWP Fraud to Increase and Maintain the Price of Drugs Outside of the Medicare Part B Context

168. The Defendant Drug Manufacturers' AWP fraud strikes well beyond Medicare Part B, adversely impacting health plans and their participants with respect to reimbursements for scores of other drugs. As described below, one such area is the use of AWPs by PBMs.

169. Health plans typically contract with intermediaries called pharmacy benefit managers ("PBMs") so that a health plan's participants can obtain brand name drugs from pharmacies or, via mail order, directly from the PBMs. In these contracts, the brand name drugs are priced at the AWP less a certain percentage "discount."

170. Pharmacy benefit managers – or "PBMs" – are fiscal intermediaries that specialize in the administration and management of prescription benefit programs. PBM clients include HMOs, employers, preferred provider organizations and other health insurers. Collectively, four PBMs comprise the significant market share of the PBM market. They are: AdvancePCS; Caremark; Express Scripts; and Medco Health. These four companies handle the drug benefits of 210 million people in the United States, or 70 percent of the nation's population.

171. For brand name drugs, PBMs use inflated "Average Wholesale Price" – or "AWP" – set by drug manufacturers as the basis for reimbursement (i) made by health plans to the PBMs for their members' drug purchases; and (ii) from the PBMs to the pharmacies for the purchases made by health plans' members. The PBMs typically contract with retail pharmacies to reimburse an amount equal to each drug's AWP, less a specified discount, plus a dispensing fee. Because the PBMs consider the contracting relationship with retail pharmacies to be confidential, health plans are never informed of the reimbursement amount to pharmacies. However, the PBM frequently pockets a "spread" or differential between charges paid to pharmacies and collected from clients. So, for example, clients may be charged the AWP minus 13 percent, but the retail pharmacy may only receive the AWP minus 15 percent, generating an undisclosed 2 percent spread for the PBM. Furthermore, as the example presented demonstrates,

PBMs are motivated to, and do place on their formulary those drugs with inflated AWPs: the greater the AWP inflation, the greater the profit to the PBM based on the 2 percent spread. A similar situation occurs for generic drug pricing based on Maximum Acquisition Cost (“MAC”) lists, as the PBM uses one MAC list to charge clients and another MAC list to reimburse pharmacies. Further, with respect to mail order prescriptions, PBMs do business with companies that have the right to repackage drugs; they are called repackagers. These repackagers assign a new NDC number to a drug and publish a higher AWP. The PBM then negotiates with the repackager a discount off the AWP and tells the health plan it has saved a certain percentage off the AWP. But because the repackager’s AWP is higher, the health plan pays more and the PBM pockets the spread between the AWP and the price paid to the repackager. PBMs also have mail order services in which case they act as the pharmacy. In this situation, the PBM keeps the spread between the AWP and the list price as there is no intermediary, like a pharmacy dispensing the drug. The PBMs keep this spread knowing that the AWPs are inflated and not the true AWP.

172. The Defendant Drug Manufacturers knew and understood that the PBM Defendants used the *Red Book* and other publications to determine the AWPs of the drugs. Because the drug manufacturers controlled the AWPs published in the *Red Book* and other compendia, the drug manufacturers knew and understood that they could help manipulate the PBMs’ profits from Plaintiffs and the classes. The purpose of artificially inflating the PBMs’ profits was to create an illegal kickback to the PBMs, funded by health plan and subscriber overpayments.

173. PBMs use the inflated AWPs set by drug manufacturers as the basis for the payments (i) made by health plans to the PBMs for their members’ drug purchases, and (ii) from the PBMs to the pharmacies for the purchases made by health plans’ members.

174. The PBMs typically contract with retail pharmacies to reimburse in an amount equal to each drug's AWP, less a specified discount, plus a dispensing fee. Because the PBMs consider the contracting relationship with retail pharmacies to be confidential, health plans are never informed of the reimbursement amount to pharmacies.

175. However, the PBMs frequently pockets a secret "spread" or differential between charges paid to pharmacies and collected from clients. So, for example, clients may be charged the AWP minus 13 percent, but the retail pharmacy may only receive the AWP minus 15 percent, generating an undisclosed 2 percent spread for the PBMs.

176. Furthermore, as the example presented demonstrates, PBMs are motivated to place on their formulary those drugs with inflated AWPs: the greater the AWP inflation, the greater the profit to the PBM based on the 2 percent spread.

177. A similar situation occurs for generic drug pricing based on MAC lists, as the PBM uses one MAC list to charge clients and another MAC list to reimburse pharmacies.

178. The PBMs deliberately utilize the inflated AWP to overcharge health plans for brand name drugs purchased by their participants and beneficiaries at retail pharmacies. An example of this practice was recently reported in the WALL STREET JOURNAL on March 30, 2003. According to the JOURNAL article, the AWP for fluoxetine is \$2.66 a pill. With a 60 percent discount off the AWP, that brings the price to \$1.06 a pill the PBM collects from the plan. Express Scripts pays the pharmacy 25 cents a pill and keeps the rest as profit. Express Scripts claims that currently its client pays 60 cents a pill, but since Express Scripts pays a pharmacy 25 cents per pill, it receives almost a 100 percent profit. And at the same time it was making this profit, Express Scripts was notifying its clients it was saving them money by having switched to fluoxetine, instead of Prozac.

D. The Defendant Drug Manufacturers' Use of AWP Fraud to Increase and Maintain Volume and Market Share For Generic and Multi-Source Drugs

179. The Defendant Drug Manufacturers' AWP fraud is most exacerbated for generic drugs or for brand name drugs for which there are biological or therapeutic equivalents.

180. Health plans and other sponsors of drug benefits contract with PBMs both so that the plan's participants can obtain *brand name* drugs from pharmacies or mail order distribution, but also so that they might receive *multi-source*, or *generic, drugs*. As with brand name drugs, reimbursement for multi-source, or generic, drugs is also related to a published average wholesale price for each generic drug manufactured and/or distributed by a generic drug company.

181. In the private payor arena, generic drug reimbursement is determined either in the same manner for brand name drugs (*i.e.*, a certain percentage "discount" off of the AWP), or is based on the amount specified as the maximum allowable cost or "MAC." MAC prices or reimbursements rates are a schedule of pricing for generically equivalent drugs based upon the listed average wholesale prices (AWPs) of competing generic drug manufacturers. The federal government originally introduced the concept of MAC reimbursement for generic medications. The CMS issues a MAC price list for generic products that have three or more manufacturers or distributors on the market. Because of this limitation, not all generics have a corresponding CMS MAC price.

182. PBMs often utilize this government-issued MAC reimbursement publication as a basis for their proprietary MAC list and supplement the list with other generic products or modify it for a variety of purposes. Sometimes, to stabilize the cost variance of different generic products of the same compound, pharmacy benefit administrators calculate a maximum allowable cost based on the list average wholesale prices of competing generic drug manufacturers (indeed, this is termed in the industry as the average average wholesale price or

“AAWP”). The resulting proprietary MAC generic drug reimbursement lists are typically based on the AAWP and, in turn, the AWP.

183. Accordingly, in the private payor arena generic drug reimbursement is closely tied to the published AWP for a generic drug. Generic drug makers are able to push market share for their generic drugs by intentionally increasing the published AWP for a generic drug with the intention to create a profit margin for others in the distribution chain. That profit margin is taken advantage of either directly (through reimbursement based upon the AWP for some plans and in some channels) or indirectly on the AWP based upon the establishment of a MAC tied to the AWP.

184. In the public payor arena under Medicare Part B, multi-source drugs or biologicals are also reimbursed on the basis of AWP. For multi-source drugs or biologicals, under Medicare Part B the AWP is equal to the lesser of the median AWP of all of the generic forms of the drug or biological, or the lowest brand name product AWP. Because reimbursement is pegged to the AWP, drug makers act in unison by elevating the AWP for all generic drugs, thereby inflating the amount of the reimbursement that occurs through Medicare Part B, including the Medicare co-payment through Part B.

185. As stated by one industry consultant:

... This situation is more pronounced with generic drugs. Many generic companies have taken advantage of this use of AWP by substantially inflating their published AWPs... [T]he system allows a retailer to acquire a drug at a low cost \$2.50 per 100 tablets, for example) while relying on a published AWP (\$20.00 or more) for its own pricing. It is not uncommon that the \$25.00 retail price for a generic drug renders a gross profit well above \$20.00 for the retailer. It is also common for the AWP of a generic product to remain stable while the actual selling price declines. . . . It is obvious that AWP is not an accurate measure of the prices manufacturers charge. It must also be noted that not all generic products will be priced similarly. Some, in fact, use the more traditional method of a 20% markup to reach an AWP. This can be a handicap for generic companies choosing this method because retailers often use the AWP as the starting point for many pricing

decisions and an artificially high AWP provides the retailer with greater profits.

186. The raising of an individual Defendant's reported AWP for a multi-source drug raises the median AWP at which the generic drug is reimbursed. As a result, the publication and reporting of fraudulent AWPs by Defendants for generic drugs squarely fits generic drugs in which the cure of unlawful AWP inflation within the activity complained of in the MCC. Moreover, while any one generic manufacturer can only effect the median generic reimbursement AWP for a product, Defendants can and do create a spread between the median AWP and the actual prices paid by reporting AWPs that are far in excess of the actual wholesale prices while simultaneously maintaining or lowering actual wholesale prices.

187. Documents produced by Defendant generic manufacturers show that they are aware of the AWPs reported by their competitors and of the actual sales price of their generic competitors and that they manipulate their own AWPs in order to gain or maintain a competitive advantage in the market for their generic products. Each Defendant generic maker or distributor competes by inflating its AWP and thereby inflating the median AWP. The natural and expected result of this "leap frogging" of increasing AWPs is that multi-source drugs have some of the highest spreads of any drugs, sometimes resulting in an AWP over 50,000% over actual costs. A few examples are set forth below:

Defendant	Multisource Drug	RedBook AWP	DOJ Determined Actual AWP	Percentage Spread
Abbott	Sodium Chloride	\$670.89	\$3.22	20,735%
Baxter	Dextrose	\$928.51	\$2.25	41,167%
Baxter	Sodium Chloride	\$928.51	\$1.71	54,199%
Boehringer Group	Leucovorin Calcium	\$184.40	\$2.76	6,581%
B. Braun	Sodium Chloride	\$11.33	\$1.49	660%
BMS Group	Etoposide (Vepesid)	\$136.49	\$34.30	298%
Dey	Albuterol Sulfate	\$30.25	\$9.17	230%
Immunex	Leucovorin Calcium	\$137.94	\$14.58	846%
Pharmacia	Etoposide	\$157.65	\$9.47	1,565%

Defendant	Multisource Drug	RedBook AWP	DOJ Determined Actual AWP	Percentage Spread
Sicor Group	Tobramycin Sulfate	\$342.19	\$6.98	4,802%
Watson	Vancomycin HCL	\$70.00	\$3.84	1,567%

188. In summary, generic or multi-source drugs are subject to fraudulent AWP manipulation as set forth in this Amended MCC.

189. The importance of AWPs to generic drugs was recently revealed in a lawsuit filed by Dey and two of the Publishers. In this lawsuit, Dey's allegations can be summarized as follows:

(a) Dey is a generic manufacturer, and generic manufacturers largely compete on price because they market products that contain the same active ingredients and are predominantly therapeutically interchangeable. (¶ 9 of Dey Complaint.)

(b) A large segment of the generic marketplace for respiratory drugs is comprised of a relatively small number of entities controlling purchase decisions. (¶ 12 of Dey Complaint.)

(c) The vast majority of prescription drug transactions – as much as 85% – are covered, in whole or in part, by third-party payor reimbursement arrangements such as managed care plans and Medicaid. (¶ 13 of Dey Complaint.) Both Medicaid and the private insurance system rely on reimbursement formulas that utilize the AWP. (¶¶ 14-16 of Dey Complaint.)

This allegation confirms Plaintiffs' allegations in this Complaint that the AWP fraud impacts private markets, not just Medicaid.

(d) Dey has an agreement with First DataBank and Medi-Span to provide the reporting services with AWP pricing information. Pursuant to this agreement (and in order to make Dey's products eligible for reimbursement through Medicaid Programs), Dey has reported WACs and AWPs. (¶¶ 26-32 of Dey Complaint.)

In each case, until the events that have resulted in the present crisis, First DataBank has (except for some inadvertent errors)

selected for listing in its published reports the AWP as suggested by Dey. For over ten years, until April 2003, no prices other than those submitted by Dey have been listed by First DataBank as AWP for Dey products in its databases [even though Dey also reported declining WACs for the products].”

(¶ 32 of Dey Complaint; *see also* ¶ 36 of Dey Complaint for similar allegation against Medi-Span.) This has also been the course of dealings between the Publishers and Dey’s competitors:

Virtually every drug manufacturer who participates in these reimbursement programs, and against whom Dey competes also communicates their suggested AWP prices to the reporting services. To the best of Dey’s knowledge, with few, if any exceptions, First DataBank and Medi-Span have selected and reported the AWP pricing exactly as suggested by these competing manufacturers.

(¶ 37 of Dey Complaint.) *See also* ¶ 47 of Dey Complaint (recounting testimony of First DataBank representative who admits that First DataBank had always accepted the AWPs suggested by the manufacturers).

(e) Providers who dispense generic drugs “are cognizant of, and are highly attentive to, AWPs as reported by the recognized industry compendia published by First DataBank and Medi-Span because of the direct relationship between the level of reimbursement anticipated for the drugs selected and the reported AWPs of those drugs.” (¶ 38 of Dey Complaint.) Indeed, Dey admits that it has relied on the publishers’ practice of treating all manufacturers equally by simply reporting whatever AWP a manufacturer submitted. Consequently, First DataBank and Medi-Span have frustrated Dey’s “reasonable expectations” by *independently reporting* an AWP different than that submitted by Dey. (¶ 39 of Dey Complaint.) These allegations become even more emphatic in a section of the Complaint titled “The Immediate Consequences of the Arbitrary Changes:”

Since reimbursement to Dey’s customers is, in Medicaid program in many states and in and [sic] insurance programs, most frequently based on the AWP as reported by the reporting services, this arbitrary and capricious reduction by First DataBank and Medi-Span in AWP would result in a drastic reduction in the reimbursement to drug providers who choose to dispense Dey’s product. Since there has not been a comparable reduction in the

AWP for Dey's competitors, there would be no comparable reduction in the reimbursement the purchasers of competitive products receive.

Because reimbursement for Dey products would be significantly reduced, but reimbursement for those competing products would remain as they have been, Dey is prevented, by First DataBank's and Medi-Span's arbitrary and capricious acts, from effectively competing in the marketplace.

In fact, within one day of learning that First DataBank and Medi-Span had arbitrarily changed Dey's AWP, Dey has already been contacted by at least nine of its customers complaining about the drastic changes and indicating that, because of those changes, the customers would not be able to purchase Dey products since they could not earn a reasonable profit from the sale of such products.

Further, at least one customer has already indicated that he had canceled all of his purchases presently on order from Dey and was, instead, buying those products from Dey's direct competitors.

..... These providers will cease to purchase and dispense Dey's drugs if the reimbursement for those drugs is a fraction of those obtained from competing companies. Because purchasing decisions are highly concentrated in this industry among wholesalers and group purchasing organizations, this scenario is playing out across the country and threatens to eliminate sales of Dey's products that are covered by Medicaid and insurance reimbursement programs.

(¶¶ 50-54 of Dey Complaint.)

190. *These allegations confirm the allegations herein that medical providers rely on spreads in dispensing (and, consequently, so do the manufacturers in order to move market share).* Further, these allegations are akin to saying: "We all committed fraud on an even basis, but now only my competitors can commit fraud; consequently, I have now suffered damage."

E. Defendants' Concealment of the Truth

191. Each Defendant concealed its fraudulent conduct from the Plaintiffs and the Class by controlling the process by which the AWPs for Covered Drugs and brand name drugs were set. Defendants prevented Plaintiffs and the Class Members from knowing what the actual pricing structures for these drugs were, and failed to inform them of the usage of free samples and the provision of other financial incentives to providers and other intermediaries to lower

their respective costs for the drugs. Moreover, Defendants' fraudulent conduct was of such a nature as to be self-concealing.

192. Each Defendant closely guarded its pricing structures and sales figures for their Covered Drugs and brand name drugs. CMS Health Care Industry Market Update (dated January 10, 2003) stated that drug "price discounts are closely guarded as competitive information." *See p. 39.*

193. Each Defendant also concealed its fraudulent conduct by instructing providers and others not to report the prices they paid for the Covered Drugs and brand name drugs, respectively.

194. Each Defendant also worked with and motivated provider and intermediary trade associations to halt any investigations or change in the AWP system.

195. Each Defendant's efforts to conceal its pricing structures for Covered Drugs and brand name drugs is evidence that it knew that its conduct was fraudulent.

196. Thus, each Defendant concealed that (i) its AWPs were highly-inflated (and were inflated solely to cause Plaintiffs and the Class to overpay for the AWPs), (ii) it was manipulating the AWPs of the AWPs, and (iii) the AWPs bore no relationship to the prices paid for, or the pricing structure of, the AWPs as they were sold to providers and others.

197. Plaintiffs were diligent in pursuing an investigation of the claims asserted in this Complaint. Through no fault of their own, they did not receive inquiry notice nor learn of the factual basis for their claims in this Complaint and the injuries suffered therefrom until recently.

F. Tolling of Applicable Statutes of Limitation

198. Any applicable statutes of limitations have been tolled by Defendants' knowing and active concealment and denial of the facts alleged herein. Plaintiffs and members of the Class have been kept in ignorance of vital information essential to knowledge of and the pursuit

of these claims, without any fault or lack of diligence on their part. Plaintiffs and members of the Class could not reasonably have discovered the fraudulent nature of the published AWPs.

199. Defendants were and continue to be under a continuing duty to disclose to Plaintiffs and the Class the fact that the published AWPs bore and continue to bear no relationship to the prices or pricing structures for Covered Drugs and brand name drugs. Because of their knowing, affirmative, and/or active concealment of the fraudulent nature of the published AWPs, Defendants are estopped from relying on any statutes of limitations.

V. EXAMPLES OF SPECIFIC UNLAWFUL CONDUCT

200. Due to acts of concealment by each Defendant, the following examples of the specific unlawful conduct engaged in by each particular Defendant are merely illustrative. They are not intended to be an exhaustive account of all of the unlawful activity engaged in by each Defendant. Instead, these allegations allege the circumstances of the wrongdoing with some detail. Additional detail is peculiarly within the Defendants' control and warrants that further discovery should proceed as to each drug identified in this Complaint as well as other drugs whose AWP is published by any Defendant.

A. Abbott

201. Abbott engages in an organization-wide and deliberate scheme to inflate AWPs. Abbott has stated fraudulent AWPs for all or almost all of its drugs, including those set forth below. The specific drugs of Abbott for which relief is currently sought in this case are set forth in Appendix A, and are identified below:

Manufacturer	Brand Name (if applicable)	Generic Name	Therapeutic Category/Usage
ABBOTT	A-Methapred	methylprednisolone sodium succinate	Anti-Inflammatory Agent Used to provide relief for inflamed areas of the body. Also used for control of allergic processes
	Aminosyn	amino acid	Nitrogen Product Used as a nutritional supplement

Manufacturer	Brand Name (if applicable)	Generic Name	Therapeutic Category/Usage
	Biaxin	clarithromycin	Macrolide (Anti-Infective Agent) Used to treat mild to moderate infections
	Calcijex	calcitrol	Hormone Used in the treatment of hypocalcemia
	Depakote	divalproex sodium	Anticonvulsant Used in the treatment of complex partial seizures
	Ery-tab	erythromycin, enteric-coated	Antibiotic Agent (Anti-Infective Agent) Used in the treatment of various infections
	Erythromycin	erythromycin base	Antiacne Agent; Anti-Infective Agent Used in the treatment of various infections
	Liposyn II	fat emulsion	Caloric Agent; Nutritional Supplement Used as a nutritional supplement
	Prevacid	lansoprazole	Proton Pump Inhibitor (Gastrointestinal Agent) Used in the treatment of duodenal ulcer and erosive esophagitis
		acetylcysteine	Mucolytic (Respiratory Agent: Diagnostic Aid) Used for certain lung conditions when increased amounts of mucus make breathing difficult
		acyclovir sodium	Anti-Infective Agent Used in the treatment of herpes infections
		amikacin sulfate	Antibiotic Agent (Anti-Infective Agent) Used to treat respiratory tract, urinary tract, bone, skin and soft tissue infections
		cimetidine hydrochloride	Gastrointestinal Agent Used in the treatment of duodenal ulcer and prevention of ulcer recurrence
		clindamycin phosphate	Anti-Infective Agent Used in the treatment of vaginal infections
		dextrose	Caloric Agent Used to increase intake of calories and fluids
		dextrose sodium chloride	Caloric Agent; Electrolyte Replenisher Used to increase intake of calories and fluids
		diazepam	Central Nervous System Agent Used to treat status epilepticus and anxiety disorders. Also used as an amnesic prior to surgical procedures
		fentanyl citrate	Central Nervous System Agent Used for anesthetic purposes

Manufacturer	Brand Name (if applicable)	Generic Name	Therapeutic Category/Usage
		furosemide	Diuretic Used in the treatment of edema associated with cirrhosis and kidney disease. Also used to manage hypertension
		gentamicin sulfate	Anti-Infective Agent Used as a general antibiotic to treat serious gastrointestinal, respiratory, bone, skin and soft tissue infections
		heparin sodium or heparin lock flush	Blood Modifier Used to prevent and treat thrombosis and pulmonary embolism. Also used as an anticoagulant in blood transfusions and dialysis procedures
		leucovorin calcium	Antianemic Agent (Blood Modifier) Used in the treatment of anemia
		lorazepam	Central Nervous System Agent Used in the treatment of anxiety disorders
		sodium chloride	Flush; Abortifacient Used to remove medicine and blockage from intravenous (IV) catheter. Also used to induce abortion
		tobramycin sulfate	Antibiotic Agent (Anti-Infective Agent) Used to treat severe infection
		vancomycin hydrochloride	Antibiotic Agent (Anti-Infective Agent) Used as a general antibiotic

1. Abbott Has Been The Target of Government Investigations

202. In connection with its scheme to inflate AWPs, Abbott has been investigated by the United States Department of Justice, Commonwealth of Massachusetts, the Office of Inspector General of the Department of Health and Human Services, the Attorney General for the State of Texas, the Attorney General for the State of California, and the State of California Department of Justice Bureau of Medi-Cal Fraud and Elder Abuse.

203. These investigations confirm that Abbott has engaged in a deliberate scheme to inflate the published AWPs for many of its drugs. According to Representative Pete Stark, the ranking member of the Congressional Ways and Means Committee:

The price manipulation scheme is executed through Abbott's inflated representations of average wholesale price ("AWP") and direct price ("DP") which are utilized by the Medicare and Medicaid programs in establishing drug reimbursements to providers. The difference between the inflated representations of AWP and DP versus the true price providers are paying, is regularly referred to . . . as "the spread." The evidence . . . clearly shows that Abbott has intentionally reported inflated prices and has engaged in other improper business practices in order to cause its customers to receive windfall profits from Medicare and Medicaid when submitting claims for certain drugs. The evidence further reveals that Abbott manipulated prices for the express purpose of expanding sales and increasing market share of certain drugs. This was achieved by arranging financial benefits or inducements that influenced the decisions of health care providers submitting Medicare and Medicaid claims.

See October 31, 2000 letter from U.S. Representative Pete Stark to Miles White, Chief Executive Officer of Abbott. (P007647-78.)

2. Abbott Controls the Published AWP for Its Products

204. Abbott has controlled and set the AWPs for its pharmaceutical products through direct communications with industry compendia during the Class Period.

3. Abbott's AWP Manipulation Benefited Providers at the Expense of the Class

205. The purpose of Abbott's manipulation was to increase the spread in order to maximize the profit to providers and other intermediaries at the expense of Plaintiffs and the Class.

a. For example, Abbott anticipated that the spread between AWP and cost would be eliminated by legislative changes in 1997. Accordingly, Abbott looked for ways to maximize the profit spread immediately. In one internal memorandum about a third party's pricing product, Abbott states:

One of GeriMed's goals of obtaining maximum profitability for its members presents an opportunity for our injectables. They think there is about an 18 month window of opportunity to promote our injectables as more profitable for their members to use because of the bigger spread between AWP and cost. Legislative changes in reimbursement are expected to do away with this spread advantage by mid 1997.

(ABT AWP/MDL 015839) (Highly Confidential).

b. In a second memorandum about this same product, Abbott states:

The purpose of these programs was to “enhance revenue and decrease cost.” *** These suggestions are made to save money through lower contract pricing or increase revenue through better spread between AWP and contract price.... The [distributor’s] program identifies the lowest cost product and ***the best spread for the particular state.***

(ABT AWP/MDL 010407-09) (Highly Confidential) (emphasis added).

206. Abbott tried to maximize spread because it understood that its customers routinely engaged in “spread shopping” – comparing Abbott’s AWPs with those of its competitors in order to determine the greatest spread (and therefore sell or administer the drug with the greatest spread). An example is a document produced by Abbott, prepared by a customer in late 1993, comparing Abbott’s proposed contract price and its published AWPs with that of Baxter’s competing generic drugs. (ABT AWP/MDL 028546) (Highly Confidential).

207. Just as Abbott motivates providers to administer drugs based on the AWP, Abbott’s 1996 Pricing Guidelines reveal that Abbott rewards PBMs based on the degree of influence they exert to drive utilization of Abbott products. (ABT AWP/MDL 053922-23) (Highly Confidential).

4. Specific Abbott AWPs Documented by the DOJ

208. In a report published by the DHHS (the “DHHS Report”; PM Rev. AB-00-86, “An Additional Source of Average Wholesale Price Data In Pricing Drugs and Biologicals Covered by the Medicare Program,” Sept. 8, 2000), the DOJ documented at least 81 instances where the published AWPs for various dosages of 16 drugs manufactured by Abbott were substantially higher than the actual prices listed by wholesalers. The chart below sets forth the 16 drugs identified by the DOJ and the spread associated with one particular dosage of each drug. These figures compare the DOJ’s determination of an accurate AWP for that particular

dosage, based upon wholesalers' price lists, with the AWP reported by Abbott in the 2001 *Red Book*.

Drug	Abbott's 2001 <i>Red Book</i> AWP	DOJ Determined Actual AWP	Difference	Percentage Spread
Acetylcysteine	\$35.87	\$21.90	\$13.97	64%
Acyclovir	\$1047.38	\$349.05	\$698.33	200%
Amikacin Sulfate	\$995.84	\$125.00	\$870.84	697%
Calcitriol (Calcijex)	\$1,390.66	\$1079.00	\$311.66	29%
Cimetidine Hydrochloride	\$214.34	\$35.00	\$179.34	512%
Clindamycin Phosphate	\$340.52	\$75.35	\$265.17	352%
Dextrose	\$239.97	\$3.91	\$236.06	6,037%
Dextrose Sodium Chloride	\$304.38	\$1.93	\$302.45	15,671%
Diazepam	\$28.50	\$2.03	\$26.47	1,304%
Furosemide	\$74.52	\$14.38	\$60.14	418%
Gentamicin Sulfate	\$64.42	\$.51	\$63.91	12,531%
Heparin Lock Flush	\$38.30	\$13.60	\$24.70	182%
Metholprednisolone Sodium Succinate	\$34.08	\$2.30	\$31.78	1,382%
Sodium Chloride	\$670.89	\$3.22	\$667.67	20,735%
Tobramycin Sulfate	\$150.52	\$2.94	\$147.58	5,020%
Vancomycin Hydrochloride	\$382.14	\$4.98	\$377.16	7,574%

(P006299-316.)

5. Additional Evidence Concerning Vancomycin

209. At least one Publisher, Medi-Span, challenged the manner in which Abbott set its AWPs for vancomycin. The following statement appeared in a February 9, 1996 faxed letter to Abbott from a representative of Medi-Span:

It appears that the only difference between these two products listed is the vial it comes in. If it is, please let us know why the \$400 plus difference in AWPs?... [T]his customer claims he can get Vancomycin for \$6 or \$7 per vial DP as opposed to the \$52.94 and \$19.50 the Abbott Vancomycin cost.

(ABT AWP/MDL 001215.)

210. The government investigation into Abbott's AWP for vancomycin identified:

prices that are routinely made available to many providers, but are far below Medicare reimbursement rates. They include 1999 prices for vancomycin, the Abbott Labs-manufactured antibiotic, which a health care provider could buy for \$76.00 but for which

the AWP upon which Medicare's reimbursement was based on was \$261.84.

See September 25, 2000 letter from U.S. Rep. Tom Bliley to the Honorable Nancy-Ann Min DeParle, Administrator of the Health Care Financing Administration. (P007015-490.)

211. For other doses of vancomycin, Abbott reported an AWP of \$68.77 as of April 2000. The DOJ adjusted it to \$8.14.

6. Additional Evidence for Amikacin

212. One published report states: "Amikacin, used to treat an infection that HIV+ people get and manufactured by Abbott, had an AWP of \$54.56. DOJ said the actual price was \$6.75." *See States Mull Suit Against Drug Companies*, www.stateline.org (April 2, 2001) (P011268-70).

7. Inflated AWPs From Abbott Price Lists

213. In response to government subpoenas, Abbott produced numerous price lists setting forth spreads between AWPs and prices offered to wholesalers, providers and other intermediaries. A review of those price lists reveals that Abbott has consistently offered hundreds of its drugs and other solutions to its customers at prices significantly below the published AWP and that the spread was of great importance to its customers. To repeat every one of those drugs and the spread offered to each specific customer here is not practical. However, set forth below in Tables 1 and 2 are a number of those drugs (not already referenced above) with spreads in excess of 100% from two specific Abbott customers.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

216. As set forth above, Abbott's scheme to inflate its reported AWPs and market the resulting spread to increase the market share of its drugs has resulted in excessive overpayments by Plaintiffs and the Class.

B. Amgen

1. The Drugs at Issue and Their Competitive Environment

217. Amgen engages in an organization-wide and deliberate scheme to inflate AWPs. Amgen has stated fraudulent AWPs for all or almost all of its drugs, including: Epojen (eopentin alfa for ESRD use),² Neupogen (filgrastim), Aranesp (darbepoetin alfa), Enbrel ([etanercept](#)), Kineret (anakrina), and Neulasta (pegfilgrastim). The specific drugs of Amgen for which relief is sought in this case are set forth in Appendix A and are set forth below and the complaint includes all NDCs for these drugs:

Manufacturer	Brand Name (if applicable)	Generic Name	Therapeutic Category/Usage
AMGEN	Aranesp	darbepoetin alfa albumi	Antianemic Agent; Blood Modifier Used in the treatment of anemia associated with chronic renal failure and/or chemotherapy
	Enbrel	etanercept	Antirheumatic Agent Used to reduce signs and symptoms of rheumatoid arthritis

² In the Medicare Part B context, reimbursement for Epojen is not based on the AWP, but rather on a specific dollar amount set by statute. However non-Medicare Part B reimbursement for Epojen is based on AWP for many Class members.

Manufacturer	Brand Name (if applicable)	Generic Name	Therapeutic Category/Usage
	Epogen	epoetin alfa	Antianemic Agent; Blood Modifier Used in the treatment of anemia associated with chronic renal failure, chemotherapy and/or HIV-infected patients
	Kineret	anak rinaihra	Antirheumatic Agent Used in the treatment of moderate to severe rheumatoid arthritis
	Neulasta	pegfilgrastim	Antineoplastic; Blood Modifier Used to decrease incidence of infection (neutropenia) in some cancer patients
	Neupogen	filgrastim	Antineoplastic; Blood Modifier Used to decrease incidence of infection (neutropenia) in some cancer and leukemia patients

217A. Amgen introduced EPOGEN® (Epoetin alfa) in 1989. EPOGEN® is indicated for the treatment of anemia in patients with chronic renal failure on dialysis. In 2001, Aranesp® (darbepoetin alfa), an erythropoietic protein with greater biological activity and a longer half-life than Epoetin alfa, was approved for the treatment of anemia in patients with chronic renal insufficiency. In 2002, Aranesp® was also approved for the treatment of chemotherapy-induced anemia. By 2003 Aranesp had sales of \$283 million.

217B. NEUPOGEN® (~~F~~ilgrastim) was approved in 1991. NEUPOGEN® is indicated for decreasing the incidence of infection associated with chemotherapy-induced neutropenia in cancer patients with nonmyeloid malignancies. In 2002, Amgen introduced Neulasta® (pegfilgrastim), a longer-acting form of ~~F~~ilgrastim approved for the same use but requiring only one injection per chemotherapy cycle.

218. Since its introduction, Aranesp has been locked into a knock-down competitive battle with Ortho Biotech's Procrit.

218A. A review of their respective websites reveals that Amgen and Ortho are targeting the exact same type of patient with respect to use of Aranesp and Procrit. Amgen describes Aranesp on its website as follows:

That's where Aranesp® can help. Aranesp® stimulates natural production of red blood cells boosting the number of red blood cells in the body, which can increase the amount of oxygen in your blood and give you more energy. And since you will need fewer shots and doctor visits, you can begin to feel less like a patient and more like a person – and get back to being you again.

Aranesp® is available by prescription only. Aranesp® has been approved by the Food and Drug Administration to treat the anemia associated with chronic renal failure (renal disease) in people with reduced kidney function or on dialysis. People who have uncontrolled high blood pressure should not use Aranesp®.

218B. Ortho promotes and describes Procrit on its website as follows:

PROCRIT® (Epoetin alfa) is for the treatment of anemia in patients who have chronic kidney disease and are on dialysis. PROCRIT has a proven safety record. Your doctor should carefully monitor your blood pressure and hemoglobin for rapid increases, which should be avoided. PROCRIT is available by prescription only and is administered by your health care provider.

(Emphasis added).

219. Thus, these two companies were targeting the exact same patients and have an incentive to compete based on the spread that they could offer physicians.

219A. Amgen's Neupogen also competed with Immunex's Leukine prior to Amgen's acquisition of Immunex. Both of these drugs are Part B covered drugs and as set forth below this competitive landscape became a breeding ground for competition based on spread or discounts off AWP. Competition also existed between Amgen's Remicade and Immunex's Embrel, which created a climate for using the spread between AWP and acquisition cost as an inducement to wholesalers and other providers.

2. Amgen's Definition and Understanding of AWP

219B. Internally, Amgen defines AWP as "the common basis for reimbursement by payors. AWP may not necessarily reflect the actual purchase price" (Press Release, "Data from Study Shows Aranesp . . .," Dec. 9th, 2002 (www.amgen.com)) or "one of the factors used by Medicare to determine payment for drug charges."

3. Amgen Controls the Published AWP for Its Products

220. Amgen has controlled and set the AWPs for its pharmaceutical products through direct communications with industry compendia during the Class Period.

4. Amgen Understands the Importance of Reimbursement Rates

220A. Amgen was well aware that its customers' profits depended on reimbursement rates for drugs, and that Amgen's own sales and profits in turn depended on its customers' reimbursement payments and profits:

Our sales depend on payment and reimbursement from third-party payors, and a reduction in the payment rate or reimbursement rate could result in decreased sales of our products.

In both domestic and foreign markets, sales of our products are dependent, in part, on the availability of reimbursement from third-party payors ... *we believe that sales of Aranesp and Neulasta are and will be affected by government and private payor reimbursement policies.* ... If reimbursement for our marketed products changes adversely or if we fail to obtain adequate reimbursement for our other current or future products, health care providers may limit how much or under what circumstances they will administer them, which could reduce the use of our products or cause us to reduce the price of our products. This could result in lower product sales or revenues ...

(Amgen 2002 Form 10-K at 43-44).

220B. The foregoing references referring to "reimbursement policies" refers to policies that use AWP as the benchmark for reimbursement.

221. Amgen also made sure its sales representatives were focused on reimbursement and customer profit motives. A senior Amgen sales manager has publicly stated:

Reps need to understand the insurance system flawlessly. They need to understand the money trail in terms of how a drug gets reimbursed, who reimburses it, and coverage or policy limitations – those are fundamental questions.”

221A. Part of that “understanding” was an explanation by Amgen sales representatives that was routinely made by sales representatives to physicians concerning profit that a physician could make by purchasing at a discount off AWP. With respect to, for example, Aranesp and

Neupogen, Amgen sales representatives either handed out calculations showing the spread off of AWP that a provider could realize by using Amgen's drugs, or orally reviewed such profits with physicians.

221B. Amgen has also established a website (www.reimbursementconnection.com) to help providers with reimbursement issues, including information on how to calculate reimbursement for Amgen drugs and Sample Reimbursement Sheets detailing how much Medicare will pay for Amgen drugs. In addition, Amgen maintains a telephone Reimbursement Hotline for providers or their office staffs to call to get help with reimbursement questions.

222. Amgen actually promotes the use of AWPs for reimbursement purposes on its website as follows:

Sample of Reimbursement Payments for Aranesp® Syringe/Vial Strengths

<u>Syringe/Vial Strength</u>	<u>Medicare</u>			
	<u>Average Wholesale Price (AWP)^{1/2}</u>	<u>85% of Medicare Allowable (AWP)</u>	<u>Payment¹ (at 80%)</u>	<u>Secondary Insurer or Patient Co-Payment² (at 20%)</u>
<u>J0880 – 25 mcg*</u>	<u>\$124.69</u>	<u>\$105.99</u>	<u>\$84.79</u>	<u>\$21.20</u>
<u>J0880 – 40 mcg*</u>	<u>\$199.50</u>	<u>\$169.58</u>	<u>\$135.66</u>	<u>\$33.92</u>
<u>J0880 – 60 mcg*</u>	<u>\$299.25</u>	<u>\$254.36</u>	<u>\$203.49</u>	<u>\$50.87</u>
<u>J0880 – 100 mcg*</u>	<u>\$498.75</u>	<u>\$423.94</u>	<u>\$339.15</u>	<u>\$84.79</u>
<u>J0880 – 150 mcg**</u>	<u>\$748.13</u>	<u>\$635.91</u>	<u>\$508.73</u>	<u>\$127.18</u>
<u>J0880 – 200 mcg*</u>	<u>\$997.50</u>	<u>\$847.88</u>	<u>\$678.30</u>	<u>\$169.58</u>
<u>J0880 – 300 mcg*</u>	<u>\$1,496.25</u>	<u>\$1,271.81</u>	<u>\$1,017.45</u>	<u>\$254.36</u>
<u>J0880 – 500 mcg†</u>	<u>\$2,493.80</u>	<u>\$2,119.73</u>	<u>\$1,695.78</u>	<u>\$423.95</u>

¹As reported in *Drug Topics Red Book®*, February 2004.

²Most private insurers base reimbursements for drugs on a percentage above or below published AWP.

* These strengths are available in either Aranesp® SingleJect® prefilled syringes or vials.

† Available only in Aranesp® SingleJect® prefilled syringe.

** These strengths are available in vials only.

222A. In the above table, Amgen recognizes the impact of an AWP-based price on a “secondary insurer” or patient making copay. Amgen thus promotes AWP all the while knowing that the posted AWP is artificially inflated as described.

5. Specific Examples of AWP Abuse

222B. At all relevant times Amgen understood that reimbursement for its drugs was dependent upon AWP. Amgen set the AWPs for its products in an arbitrary manner that rendered AWP to be a fictitious number in that it failed to account for rebates, volume discounts and other incentives provided to physicians and others purchasing Amgen drugs.

223. Both Procrit and Aranesp are Part B covered drugs, hence given the competition between the two, one clear way to increase market share was to increase the spread and hence the profit to providers. Indeed at Aranesp’s launch to the oncology market Amgen sales representatives had ready at their fingertips information concerning Aranesp’s AWP, the Medicare reimbursement amount, WAC, WAC minus discounts and the “profit” created by the spread between Medicare reimbursement and net acquisition cost.

223A. It was intended by Amgen’s top sales executives that its sales force would use this “profit” as a basis for marketing Aranesp.

223B. Examples of the improper use of AWPs by Amgen are set forth below. For example, to increase its market share Amgen in 2003 offered Aranesp to customers with a rebate or discount of up to 30% off of list price, which in itself is 20%-25% off of the published AWP. Thus, Amgen was offering spreads of 50% or more off of the published AWP on Aranesp. These spreads are being offered while Amgen is promoting use of AWP on its own website.

224. On or about July 18, 2003, Amgen extended this discount offer through July 15, 2004. Thus, even in the face of this litigation, Amgen was offering substantial discounts which rendered the reported AWPs inflated and without basis.

224A. This spread on Aranesp was created at the time of its introduction, and as Amgen has published posted an AWP that created at times at least a 40% spread between the estimated cost to a dispenser and AWP. Given the significant cost of Aranesp this is about \$300 per unit for most NDCs. If a typical treatment involves two doses twice a month for a three- to four-months period, the cost of this spread is \$1800 - \$2400 per patient. For a Medicare patient this could increase co-payments by \$360 - \$480.

224B. On information and belief, tThe use of rebates and off-invoice discounts did not start in 2003 but occurred shortly after Aranesp was introduced in 2002. The allegation is based on (a) the fact that the competition between Amgen and Ortho existed before 2003, (b) that Ortho was heavily engaged in its own conduct directed at marketing the spread and Amgen needed to respond in kind, (c) Amgen was offering "introductory" discounts that inflated AWP, and (d) as noted above Amgen sales representatives were armed with calculations showing the profit created by the Aranesp spread. Ortho, at national sales meetings, authorized its sales and marketing representatives to provide free samples as a means of lowering acquisition costs to providers. Ortho also used inducements such as educational and promotional grants to win over clinics and other providers and as credit memos which were inducements for a clinic or provider to use Procrit exclusively. Amgen sales representatives learned of these efforts and reacted to them by offering inducements of their own. These inducements included rebates based upon volume used by the practitioner.

225. Amgen's efforts at using inflated AWPs to increase market share were successful as Aranesp sales have steadily increased.

225A. Amgen's AWP-related manipulation did not stop at Aranesp. Prior to its acquisition of Immunex, Amgen competed with Immunex with respect to its drug Neupogen and Immunex's IL Leukine. Documents produced by Immunex reveal that Immunex was marketing IL Leukine based on the spread, promoting its spread of \$80.60 per vial as an advantage over

Amgen's \$51.61 spread per vial. At the time of this spread marketing by Immunex, Amgen published an AWP for Neupogen of roughly \$263.30, and was selling its product to doctors at \$201.16. This created a spread of 31% off of AWP which, given the high price of each vial, would have a substantial impact on co-payors and third-party payors, and provided a handsome profit to providers.

225B. Amgen's use of the spread did not go unnoticed by competitors. In an internal memorandum, employees of a competitor, Centecor, wrote in the context of "reimbursement issues" that doctors have a "fear of audit and not being perceived as infusing only for profit," i.e., using infusion where other treatments were available, but noted that Amgen had no issues in encouraging oncologists to choose drugs based on the spread:

We need to do a stronger job up front driving home the patient benefit of PMP. One of the other reasons I see doctors hitting a point and not moving forward is fear of audit and not being perceived locally as infusing only for profit. An example of what goes on in other specialties might be of benefit – personally I would use an Amgen or Immunex oncology product and show the AWP versus payment. As you know these companies have been telling Rheums it is unethical to receive payment for prescribing an agent but have no problem promoting this concept to oncologists. We don't need to make this a big production—if you put the slide up with the product and company the attendees can connect the dots.

226. The foregoing e-mail is in effect competitor intelligence confirming that Amgen was marketing the spread on its products sold to oncologists, which include Aranesp, Neulasta and Neupogen.

226A. Spreads created for Neupogen are set forth below for a 300ml dose. Not only are the spreads sizable, but reported AWPs increased faster than the real AWP, thus making the reported AWPs in later years even more inflated. This increase in spread is the direct result of an effort to induce physicians to use Neupogen due to the increase in the spread:

<u>Year</u>	<u>Reported AWP</u>	<u>Real AWP</u>	<u>Spread in Dollars</u>	<u>Percentage</u>
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<u>1997</u>	<u>\$161.30</u>	<u>\$125.09</u>	<u>\$36.21</u>	<u>28</u>
<u>1998</u>	<u>\$165.30</u>	<u>\$130.02</u>	<u>\$35.28</u>	<u>27</u>
<u>1999</u>	<u>\$180.40</u>	<u>\$134.81</u>	<u>\$45.91</u>	<u>34</u>
<u>2000</u>	<u>\$188.50</u>	<u>\$140.49</u>	<u>\$39.88</u>	<u>28</u>
<u>2001</u>	<u>\$197.80</u>	<u>\$148.62</u>	<u>\$49.18</u>	<u>33</u>
<u>2002</u>	<u>\$207.50</u>	<u>\$149.60</u>	<u>\$57.90</u>	<u>38</u>

226B. Spreads for the 10,000 u/ml ten pack for Epopen were historically approximately 33%, but beginning in January 2000 Amgen implemented a series of AWP increases so that by 2002 the spread increased to 42%. The increase in spread was designed to increase market share.

227. AWPs for the 4,000 units/millileterml of Epopen were also inflated with spreads between 92% and 105%. AWPs for this drug/dose increased while costs to the provider decreased. Similarly, the ten pack 4,000 units/ml dose started in 1997 with a spread of 26% that increased to 47% over time.

227A. Amgen has also caused artificially inflated AWPs to be published for its top-selling drug Enbrel. Originally, the spread between AWP and acquisition cost was 25%. This spread has steadily increased over time such that for some doses, the spread is 32% to 40%. Amgen has created this spread to encourage promotion and use of Enbrel by those in the distribution chain.

6. Amgen Rebates on Epopen

227B. In addition to marketing the spread, Amgen has utilized other impermissible inducements to stimulate sales of its drugs. These inducements were designed to result in a lower net cost to the provider while concealing the actual wholesale price beneath a high invoice price.

228. A 1993 OIG Report detailed how Amgen gave substantial year-end rebates to its customers based on their purchases of Epopen. The report noted that Medicare and Medicare beneficiaries did not receive the benefit of any rebates; all monies remained with the provider. There was no way to provide for any rebates on Medicare claim forms, and Amgen's rebates were not provided until year-end:

[T]he effect of the rebates is that it reduces the actual cost of EPO to a dialysis facility, thus increasing their gross profit. Presently, the rebates represent price reductions which benefit the facilities exclusively.

(“Review of Epogen Reimbursement,” (OIG A-01-02-00506 at 7-8)).

228A. By utilizing hidden inducements, Amgen provided purchasers with substantial discounts meant to gain their patronage while maintaining the fiction of a higher wholesale price.

229. Amgen’s scheme to inflate its reported AWPs and market the resulting spread to increase the market share of its drugs and its use of hidden rebates and financial inducements to its customers has resulted in excessive overpayments by Plaintiffs and the Class.

7. Amgen Concealed Its AWP Manipulation

229A. Amgen deliberately acted to conceal its fraudulent reporting and marketing of the AWP spread. For example, as noted above, Amgen gave rebates to its Epogen customers which effectively lowered the true price charged. When OIG asked Amgen for data on its total sales or the total amount of Epogen rebates, Amgen refused to provide such data. (“Review of Epogen Reimbursement,” (OIG A-01-02-00506 at 7-8)).

230. In September 2001, the GAO reported that epoetin alfa accounted for the second highest percentage of Medicare expenditures on drugs in 1999, accounting for 9.5% of spending for prescription drugs by Medicare in 1999 and for 3.4% of all Medicare allowed services.

230A. As set forth above, Amgen’s scheme to inflate its reported AWPs and market the resulting spread to increase the market share of its drugs has resulted in excessive overpayments by Plaintiffs and the Class.

C. AstraZeneca

231. AstraZeneca has engaged in an ongoing deliberate scheme to inflate AWPs. The drugs at issue for this defendant are identified in Appendix A and summarized below:

Manufacturer	Brand Name (if applicable)	Generic Name	Therapeutic Category/Usage
ASTRAZENECA	Accolate	zafirlukast	Leukotriene Antagonist (Respiratory Agent) Used in the treatment of asthma
	Armidex	anastrozole	Antiestrogen (Antineoplastic: Hormonal Agonist/Antagonist) Used in the treatment of breast cancer in postmenopausal women
	Atacand	candesartan cilexetil	Angiotension II Receptor Antagonist (Cardiovascular Agent) Used in the treatment of hypertension
	Atacand HCT	candesartan cilexetil-hydrochlorothiazide	Angiotension II Receptor Antagonist With Diuretic (Cardiovascular Agent) Used in the treatment of hypertension
	Casodex	bicalutamide	Antineoplastic Used in the treatment of prostate cancer
	Diprivan	propofol	General Anesthetic Used in the induction or maintenance of anesthesia as part of balanced anesthetic technique
	Entocort	budesonide	Glucocorticoid Used in the treatment of Crohn's disease
	Nexium	esomeprazole magnesium	Proton Pump Inhibitor (Gastrointestinal Agent) Used in the treatment of heartburn and erosive esophagitis
	Nolvadex	tamoxifen citrate	Antiestrogen (Antineoplastic: Hormonal Agonist/Antagonist) Used in the treatment or prevention of breast cancer
	Prilosec	omeprazole	Proton Pump Inhibitor (Gastrointestinal Agent) Used in the treatment of gastric and duodenal ulcers, gastroesophageal reflux disease and erosive esophagitis
	Pulmicort	budesonide (inh)	Glucocorticoid Used for maintenance treatment of asthma
	Rhinocort	budesonide (nasal)	Glucocorticoid Used in the treatment of allergic rhinitis
	Seroquel	quetiapine fumarate	Antipsychotic Agent (Psychotherapeutic Agent) Used in the treatment of schizophrenia
	Toprol	metoprolol succinate	Beta Adrenergic Blocking Agent (Cardiovascular Agent) Used in the treatment of hypertension, angina pectoris and heart failure

Manufacturer	Brand Name (if applicable)	Generic Name	Therapeutic Category/Usage
	Zestril	lisinopril	Angiotension Converting Enzyme Inhibitor (Cardiovascular Agent) Used in the treatment of hypertension and heart failure
	Zoladex	goserelin acetate	Gonadotropin Releasing Hormone Analogue (Antineoplastic: Hormonal Agonist/Antagonist) Used in the treatment of prostate and advanced breast cancer
	Zomig	zolmitriptan	Serotonin Receptor Agonist (Migraine Preparation) Used in the treatment of migraines

1. AstraZeneca Has Been the Target of a Government Investigation

232. In connection with its scheme to inflate AWPs, AstraZeneca has been investigated by the United States Department of Justice. In January 2002, a federal grand jury in Wilmington, Delaware returned an indictment accusing a New Jersey doctor of conspiring with AstraZeneca to resell free samples of Zoladex® that AstraZeneca sales representatives had given the doctor. The indictment alleges that AstraZeneca (i) sold Zoladex® to the New Jersey doctor and others at prices substantially below the AWP reported by AstraZeneca, and (ii) provided the New Jersey doctor with materials showing how much more profit he could make by using Zoladex® instead of its competitor, Lupron®.

233. In response to the government's subpoena, AstraZeneca appears to have produced documents related to Zoladex only.

1. AstraZeneca's Definition and Understanding of AWP

234. In AstraZeneca's Guide to Coverage and Reimbursement, AstraZeneca defines AWP as follows:

Average Wholesale Price (AWP): The composite wholesale price charged on a specific commodity that is assigned by the drug manufacturer and is listed in either the Red Book or Blue Book. AWP is often used by third-party payers as a basis for reimbursement.

(AZ0052597) (Confidential). Thus, by its own definition, AstraZeneca recognizes that: (i) AWP should be an average of actual wholesale prices; (ii) the drug manufacturers control the published AWP; and (iii) the published AWPs directly affect the payments made by the Class.

2. AstraZeneca Controls the Published AWP for Its Products

235. AstraZeneca has controlled and set the AWPs for its pharmaceutical products through direct communications with industry compendia during the Class Period. In one internal marketing memorandum, AstraZeneca recommended:

We take a price increase in December 1995. By doing this, we can inform the Red Book of this increase and it will go into the Red Book for January 1996. This is critical, so that the state Medicare carriers can recognize our new price in January. Typically, the state carriers use the January Red Book and the July Red Book for their reimbursement price of Medicare reimbursed products. Last year when we took the price increase in February there were some Medicare carriers who did not change their reimbursement price until September. Also TAP notifies Red Book 1 month before the price change. We are at a competitive disadvantage with our audience.

(AZ0021838) (Highly Confidential).

3. AstraZeneca's AWP Manipulation Benefited Providers at the Expense of the Class

236. The purpose of AstraZeneca's manipulation was to increase the spread in order to maximize the profit to providers and other intermediaries at the expense of Plaintiffs and the Class.

a. In one internal marketing memorandum, AstraZeneca recognized the profits to providers from the inflation of AWPs: "The market we are in wants a more expensive Zoladex, because the doctor can make more money." (AZ0021838) (Highly Confidential).

b. Similarly, in its agreements with PBMs, AstraZeneca guaranteed that it would maintain a spread between AWP and AWC (average wholesale cost) in order to ensure a profit to PBMs at the expense of the Class. (AZ0036207) (Highly Confidential). For example, in its agreement with Caremark, AstraZeneca stated:

ZENECA WILL REIMBURSE CAREMARK FOR THE DIFFERENCE BETWEEN THE AMOUNT COLLECTED BY CAREMARK ON EACH PATIENT UNIT SOLD AND AWP AT THE TIME THE UNIT WAS DISPENSED. CAREMARK WILL HAVE EXERCISED BEST EFFORTS TO COLLECT THE FULL AWP FROM THE 3RD PARTY PAYER AND THE PATIENT PRIOR TO SUBMISSION TO ZENECA.

(AZ0036208) (Highly Confidential).

c. AstraZeneca recognized that its practices were at the expense of the Class: BECAUSE OF OUR STEEP DISCOUNTING, NEARLY HALF THE PROFIT TO BE REALIZED WITH ZOLADEX IS PAID BY MEDICARE. AND SINCE MEDICARE IS THE QUICKEST AND MOST DEPENDABLE PAYOR, THIS WAS SEEN AS AN ENORMOUS BENEFIT. THE OTHER HALF OF THE PROFIT WAS FROM THE PATIENT CO PAY OR SECONDARY INSURANCE

(AZ0037011) (Highly Confidential).

AstraZeneca Manipulated and Marketed the AWP for Zoladex

237. AstraZeneca stated an inflated AWP for Zoladex and marketed the resulting spread during the Class Period. AstraZeneca's documents reveal an intense competition with TAP Pharmaceuticals and its drug Lupron, focusing primarily on the spreads available to physicians between Zoladex and Lupron.

238. For instance, one internal chart touts the greater spread that can be reaped from the inflated AWP for Zoladex over the AWP for Lupron:

	AWP	AWP minus 5%	Current Cost (1 depot)	Return to Practice 1 depot	Current Max Discount 29.5% vs 50%	Return to Practice at Max.
Lupron 3-month depot	\$1,622.68	\$1,541.55	\$1,297.50	\$244.05	\$915.00	\$626.55
Zoladex 3-month depot	\$1,231.53	\$1,169.95	\$985.22	\$184.73	\$492.61	\$677.34

(AZ 0055816) (Highly Confidential).

239. Another document announcing new pricing for Zoladex states:

With a purchase of 72+ depots of ZOLADEX and the additional 2% for paying within 30 days yields the doctor a \$133.67 profit margin with ZOLADEX vs \$133.50 with a purchase of 101+

depots of Lupron. For those offices that purchase between 60-100 depots of Lupron monthly, they can increase their profit margin greatly by purchasing ZOLADEX.

(AZ 0037019) (Highly Confidential).

240. Moreover, AstraZeneca repeatedly tried to educate providers regarding the Medicare reimbursement system and the benefits to the providers for Zoladex utilization. For example in a document sent to providers AstraZeneca states:

The following is a cost comparison of Zoladex® vs Lupron® 7.5 mg where Zoladex® is purchased under the buying power of the Urology Purchasing Group, St. Louis, Mo. The calculations reflect prices/discounts effective as of 2/1/94.

	ZOLDEX	LUPRON			
Quantity	1	1-11	12-25	26-50	Your Office
Direct Drug Cost	\$245.97	\$371.00	\$360.99	\$352.50	\$
Medicare \$ Claim	\$344.76 x 80%	\$463.75 x 80%	\$463.75 x 80%	\$463.75 x 80%	\$463.75 x 80%
Medicare Payment to MD	\$275.81	\$371.00	\$371.00	\$371.00	\$371.00
Patient / 3rd Party Payment*	\$344.76 -275.81 \$ 68.95	\$463.75 -371.00 \$ 92.75	\$463.75 -371.00 \$ 92.75	\$463.75 -371.00 \$ 92.75	\$463.75 -371.00 \$ 92.75
Medicare Claim Direct Drug Cost	\$344.76 -245.97 \$ 98.79	\$463.75 -371.00 \$ 92.75	\$463.75 -360.00 \$103.75	\$463.75 -352.50 \$111.25	\$463.75 \$
Total Profit Per Injections					
Difference		\$ 6.04	\$ 4.96	\$ 12.46	\$
Percent Profit per Injection	40%	25%	29%	32%	—%
Additional Cost outlay of Lupron vs Zoladex (Direct Cost vs Direct Cost)		\$125.03	\$114.03	\$106.53	\$

ILLUSTRATION: If your office uses between 12 and 25 Lupron® units per month, your total "profit" per injection, over Zoladex, is \$4.96 but your additional outlay per Lupron injection is \$114.03. This represents an unnecessary tie up of corporate monies. Based on 12 Lupron injections per month, your office has "tied up" \$1,368.36 to achieve a "profit" of \$59.52. In this example, Zoladex represents a 40% return on investment vs. 29% for Lupron.

* Calculations assume a 100% collection of monies from patient or 3rd party. If Lupron® is used instead of Zoladex® and the 20% is not collected, then the office has lost \$23.80 per injection (\$92.75 - \$68.95 = \$23.80).

01-25-0418

(AZ0046085) (Highly Confidential).

241. Internal AstraZeneca documents reveal that AstraZeneca was directly marketing the spread to physicians. A memo announcing price changes for Zoladex states:

We have raised AWP and AWC by 7% and have increased our discount level higher at all purchasing tiers.

Pricing on Zoladex 3-month is as follows:

Discount		AWP	Cost
1-5 depots	0	1206.49	966.79
6-11 depots	11	1206.49	860.44
12-23 depots	15	1206.49	821.77
24-47 depots	17	1206.49	802.44
48-59 depots	20	1206.49	773.43
60-71 depots	22	1206.49	754.10
72-96 depots	24	1206.49	734.76
96-191 depots	25	1206.49	725.09
192 +	30	1206.49	676.75

Zoladex AWP has been priced at a 5% premium above 3 times the Zoladex 1-month depot. The discount levels have been increased also.

(AZ 0024566-67.)

242. Thus, at the same time AstraZeneca was raising the AWP for Zoladex, it was lowering the real price to providers (by giving bigger discounts), which served to widen the spread.

243. Another document sets forth the difference between the purchase price and the AWP at various volume levels. Note that even with no volume discount, a provider is still making at least a \$71.00 profit per unit on Zoladex ($\$358.55 - \$286.84 = \$71.71$):

NEW LOWER CASE QUANTITY DISCOUNT
ZOLADEX PRICING

UNITS AWP COST DISCOUNT LESS 2%

1-5	\$358.55	\$286.84	0%	\$281.10
6-11	\$358.55	\$269.63	6%	\$264.24
12-23	\$358.55	\$261.02	9%	\$255.80
24-47	\$358.55	\$252.42	12%	\$247.37
48-59	\$358.55	\$243.81	15%	\$238.93
60-71	\$358.55	\$235.21	18%	\$230.50
72+	\$358.55	\$229.47	20%	\$224.88

(P003060.)

244. The same document goes on to tout the practice's ability to make more profit, or return on investment, by exploiting the AWP scheme:

Thank you for your time and listening ear on Monday, April 17. As discussed, I am offering a proposal to switch Lupron patients to Zoladex. Zeneca Pharmaceuticals now has new volume pricing, with a 20% maximum discount, for Zoladex. What this will offer the practice is an opportunity to save money, realize a better return on investment, achieve the same profit you currently have with our competitor and free up a substantial amount of working capital. Zoladex will also save the patient money and the system money.

Based on a comparison of Zoladex and Lupron, if 480 depots are used annually Zoladex will save the practice \$57,177.60 a year. Your dollar return to the practice is now slightly higher with Zoladex. This rate of return for Zoladex is now 59% compared to Lupron's 39%

(P003058.)

245. Another AstraZeneca document even more explicitly demonstrates to providers how they can profit from the AWP scheme, in excess of \$64,000 per year:

ZOLADEX		
Direct Pricing	Medicare AWP	\$\$Return / % Return
72+ \$224.88	\$358.55	\$133.67 59%
72x\$224.88=\$16,191.38	72x\$358.55=\$25,815.60	\$9,624.24 59%
<i>based on your use of 480 depots annually, with our 2% discount these are the comparisons</i>		
\$107,942.40	\$172,104.00	\$64,161.60 59%

(P003058.)

246. According to a September 2001 GAO report, the discount from AWP for medical providers who purchased AstraZeneca's Zoladex and billed Medicare was between 21.9% and 22.3%. ("Payments for Covered Outpatient Drugs Exceed Providers' Cost, Sept. 2001")

(P005546-78).)

247. AstraZeneca, through its employees and agents, also provided millions of dollars worth of free samples of its drugs to providers. The free samples would be used to offset the total cost associated with purchases of its drugs, thereby increasing the spread, while also concealing the actual cost of the drug from Plaintiffs and the Class. Moreover, at least as to Zoladex®, AstraZeneca sales representatives specifically told providers that they could and should bill for the free samples.

248. A written proposal from AstraZeneca Sales representative Randy Payne dated July 17, 1995 encourages a urology practice to switch all of their patients to Zoladex and states: “AS AN ADDED INCENTIVE, ZENECA WILL PROVIDE YOU WITH 50 FREE DEPOTS (over \$11,900 worth of product) FOR THE INITIAL CONVERSION TO ZOLADEX.” (P003059.)

249. As set forth above, AstraZeneca’s scheme to inflate its reported AWPs for Zoladex, market the resulting spread, and channel to providers “free” goods – all in order to increase the market share of its drugs – has resulted in excessive overpayments by Plaintiffs and the Class.

D. The Aventis Group (Aventis, Pharma, Hoechst and Behring)

250. Aventis engages in an organization-wide and deliberate scheme to inflate AWPs. Aventis has stated fraudulent AWPs for all or almost all of its drugs, including those set forth below. The specific drugs of Aventis for which relief is sought in this case are set forth in Appendix A and are as follows:

Manufacturer	Brand Name (if applicable)	Generic Name	Therapeutic Category/Usage
AVENTIS GROUP (Aventis, Pharma, Hoechst and Behring)	Allegra	fexofenadine	Antihistamine Used for the relief of symptoms of seasonal allergic rhinitis
	Allegra-D	fexofenadine pseudoephedrine	Antihistamine Used for the relief of symptoms of seasonal allergic rhinitis

Manufacturer	Brand Name (if applicable)	Generic Name	Therapeutic Category/Usage
	Amaryl	glimepiride	Antidiabetic Used to lower blood glucose in Type II diabetes patients
	Anzemet	dolasetron mesylate	Antineoplastic Used to prevent nausea and vomiting after chemotherapy or operation
	Arava	leflunomide	Antirheumatic Used in the treatment of active rheumatoid arthritis
	Azmacort	triamcinolone acetonide (inh)	Steroidal Anti-Inflammatory Agent (Respiratory Agent) Used for maintenance treatment of asthma
	Calcimar	calcitonin salmon	Parathyroid Agent Used in the treatment of blood calcium levels and to increase the level of calcium in the bones
	Carafate	sucralfate	Duodenal Ulcer Adherent Complex (Gastrointestinal Agent) Used in the treatment and maintenance therapy of duodenal ulcer
	Cardizem	diltiazem	Calcium Channel Blocker (Cardiovascular Agent) Used in the treatment of angina and hypertension
	Gammar PI.V.	immune globulin	Immunizing Agent Used as a maintenance therapy in patients with compromised immune systems
	Intal	cromolyn sodium	Antiasthmatic Used to treat allergic rhinitis and severe perennial bronchial asthma
	Nasacort	triamcinolone acetonide (nasal)	Steroidal Anti-Inflammatory Agent (Nasal Preparation) Used for nasal treatment of allergic rhinitis symptoms
	Taxotere	docetaxel	Antineoplastic Used in the treatment of breast or lung cancer after failed chemotherapy
	Trental	pentoxifylline	Blood Viscosity-Reducing Agent (Blood Modifier) Used to improve the flow of blood through blood vessels

1. Aventis Has Been the Target of Government Investigations

251. In connection with its scheme to inflate AWPs, Aventis has been investigated by the United States Department of Justice, the Office of Inspector General of the Department of Health and Human Services, the Commerce Committee of the U.S. House of Representatives, the Attorney General for the State of Texas, the Attorney General for the State of California, and the State of California Department of Justice Bureau of Medi-Cal Fraud and Elder Abuse.

1. Aventis' Definition and Understanding of AWP

252. Internal documents recently produced by Aventis reveal the definition of AWP used and understood by Aventis and its predecessor companies. Specifically, a November 1992 internal newsletter at Armour Pharmaceutical Company (a predecessor company to Centeon LLC, later known as Aventis Behring) states:

“AWP” is common language among insurance carriers (state, federal and private). The acronym stands for Average Wholesale Price. AWPs are set by manufacturers as a “suggested retail” for the products they produce. *These figures represent a reasonable profit margin to healthcare providers and as such are widely referenced by insurance carriers when setting reasonable and customary rates of reimbursement.*

Average Wholesale Prices are printed in Red Book Drug Topics and Blue Book. Both serve as data resources to all state Medicaid programs. Each publication lists the drugs by brand name in alphabetical order with its corresponding descriptions.

(ABAWP 008990-91) (Highly Confidential) (emphasis added).

253. Aventis possessed the *Red Book's* definition of Average Wholesale Price:

Average wholesale price (AWP) is the standardized cost of a drug, which managed care plans frequently use for determining drug benefits. The AWP is determined through reference to a common source of price information, such as the American Druggist's *Blue Book*, which lists the costs charged for an undiscounted drug to a pharmacy by a large group of pharmaceutical wholesale suppliers. AWP's are set by pharmaceutical manufacturers and supplied to all pricing data banks for publication.

(ABAWP 012067) (Highly Confidential).

2. Aventis Controls the Published AWP for Its Products

254. Aventis controlled and set the AWPs for its pharmaceutical products through direct communications with industry compendia during the Class Period.

a. For example, on December 29, 1997, Rhone-Poulenc Rorer (a subsidiary of Rhone Poulenc SA, which merged with Hoechst AG to form Aventis in 1999) submitted a list of AWP price increases effective January 1, 1998 to both Medi-Span and First Data Bank. Aventis instructed Medi-Span and First Data Bank to “change [their] records accordingly to reflect the new prices.” (AV-AAA-001054) (Confidential). Similar letters requesting price changes for 1999 were sent to Medi-Span and First Data Bank by Aventis on December 29, 1998. (AV-AAA-001047) (Highly Confidential), (AV-AAA-001050) (Highly Confidential), and price changes for 1997 on December 23, 1996 (AV-AAA-001066) (Highly Confidential).

b. An April 1, 1998 letter from Centeon notifies Medical Economics (the *Red Book*) that effective April 1, 1998, it “has raised AWP pricing” for Bioclare and Monoclare. (ABAWP 005314) (Highly Confidential).

3. Aventis’ AWP Manipulation Benefited Providers at the Expense of the Class

255. The purpose of Aventis’ manipulation was to increase the spread in order to maximize the profit to providers and other intermediaries at the expense of Plaintiffs and the Class.

256. Aventis knew that AWP manipulation, and the related marketing of an AWP spread, was improper. An internal Aventis (Centeon) document, in pertinent part, states – in large, bold print:

ATTENTION!
SELLING AGAINST AWP

This is not an option.

Traditionally, some manufacturers have promoted differences in AWPs as a means to sell their products. Centeon does not do this,

and we hope to hear from you if you learn that any other manufacturer (sic) are using this tactic.

Some pharmaceutical manufacturers set high AWPs as a means of securing market shares for their drugs. Although not illegal, the intensity of government scrutiny of this and other pharmaceutical manufacturer pricing practices is increasing. The inspector general is looking at prices for big-ticket drugs

At the risk of being redundant it is imperative to stress that AWP can not (sic) be used in the content of selling any of our products. If you are made aware, either orally or through written correspondence, of anly manufacturer using this form of sales tactic immediately report such findings to Gene Hull and appropriate steps will be taken.

(ABAWP 000855) (Highly Confidential).

257. Nonetheless, Aventis (Centeon) routinely promoted differences in AWPs in marketing its numerous products. In seminar materials used in conjunction with an "Oncology University Anzemet Workshop" held in 1998, Aventis explained to attendees how its AWP spread could be exploited. Aventis offered the following definition and example of AWP spread:

SPREAD

- Difference between acquisition cost (AC) and reimbursement (Profit, Margin, etc.).
- Example for Anzemet
 - AC = \$68 for 100 mg vial
 - AWP = \$166.50
 - AWP - 5% = \$158.18
 - 80/20 = \$126.54/\$31.64
 - Spread = \$58.54 + \$31.64 = \$90.18

(AV-AAA-02242-56) (Highly Confidential).

258. Aventis, through its employees and agents, also provided free samples of its drugs to providers. (ABAWP 000089) (Highly Confidential) (ABAWP 000811) (Highly Confidential). The free samples would be used to offset the total cost associated with purchases of its drugs,

thereby increasing the spread, while also concealing the actual cost of the drug from Plaintiffs and the Class. In fact, a 1995 “SALES AND FREE GOODS STATUS” memo reveals that Aventis (Armour) issued millions of “free goods units” to a single customer alone. (ABAWP 000220-25) (Highly Confidential).

259. Further, just as Aventis motivates providers to administer drugs based on the AWP, Aventis rewards PBMs based on the degree of influence they exert to drive utilization of Aventis products. (AV-AAA-000197-99) (Highly Confidential).

4. Specific Aventis AWPs Documented by the DOJ

260. In a report published by the DHHS (AB-00-86), the DOJ documented at least 15 instances where the published AWPs for various dosages of 4 drugs manufactured by Aventis were substantially higher than the actual prices listed by wholesalers. The chart below sets forth the 4 drugs identified by the DOJ and the spread associated with one particular dosage of each drug. These figures compare the DOJ’s determination of an accurate AWP for that particular dosage, based upon wholesalers’ price lists, with the AWP reported by Aventis in the 2001 *Red Book*.

Drug	2001 <i>Red Book</i> AWP	DOJ Determined Actual AWP	Difference	Percentage Spread
Anzemet Injectable (dolasetron mesylate)	\$166.50	\$74.08	\$92.42	125%
Factor VIII/ Bioclate	\$1.25	\$.91	\$.34	37%
Factor VIII/ Helixate	\$1.18	\$.78	\$.40	51%
Gammaglobulin (immune globulin)	\$400.00	\$296.67	\$103.33	35%

(P006299-P006316).

261. An OIG report (*see* “Medicare Reimbursement of Prescription Drugs,” OEI-03-00-00310, Jan. 2001) further revealed that: (i) the AWP for all immune globulin 5 mg doses listed in the 1997 *Red Book* were inflated by an average spread of 32.21%; (ii) a 10 mg dose of Anzemet had a Medicare Median of \$14.82 and a Catalog Median of \$8.29, resulting in a spread

of 78.76%; and (iii) a 20 mg dose of Taxotere had a Medicare Median of \$283.65 and a Catalog Median of \$8.29, resulting in a spread of 18.75%. (P006398-006424).

5. Additional Evidence Concerning Anzemet

262. Aventis distributed a “Reimbursement Spreadsheet” to be utilized by its sales personnel to demonstrate to “private practice office” customers the “financial advantages” of its drug, Anzemet, compared to Zofran and Kytril based on Aventis’ established AWP and acquisition price (total reimbursement through Medicare). (AV-AAA-001190-93) (Highly Confidential). Aventis also communicated to its sales staff on December 7, 1998 that “Anzemet still [held] the advantage on spread” following a Kytril price increase. (AV-AAA-002291) (Highly Confidential).

263. Another Aventis internal document also addresses how a particular Aventis customer might increase its margin choosing Anzemet over the competition:

Cost and Reimbursement: OnCare has negotiated a very favorable contract with Hoechst Marion Roussel [an Aventis predecessor company], manufacturer of Anzemet. Our cost from OTN for the Anzemet 100 mg/ml vial is reduced from approximately \$70 ea. to \$62.50. In addition there will be quarterly rebates further reducing the cost to \$61.25. The AWP is \$149.88, making the margin \$88.63. Additional returns can be realized by using 1.8 mg/kg as recommended in the package insert. For example, for a patient weighing 70Kg, the dose is 126 mg, requiring 2 vials. Since the vial is single use, you may bill for both vials: total cost is \$122.50, the AWP is \$299.76, the net is \$177.26 (assuming reimbursement at AWP). By comparison the current margin for 0.7 of Kytril is \$54.89. For 1 mg it is \$78.42. If there is a price increase in 1999 (which we expect) our prices are protected, however the AWP will go up, further increasing the margin. The contract makes Anzemet the preferred 5-HT3 antiemetic drug for OnCare.

(AV-AAA-001523) (Highly Confidential). Other customers received promotional materials reflecting a significant spread between the unit price and AWP for Anzemet – and touting a “Reimbursement and Patient Assistance Program Hotline.” (AV-AAA-001619-23) (Confidential).

264. A government investigation revealed similar inflated pricing implemented by Aventis with respect to the injectable form of Anzemet. In a September 28, 2000 letter to Alan F. Holmer, President of the Pharmaceutical Research and Manufacturers of America, U.S. Rep. Pete Stark provided a synopsis of the scheme implemented by Aventis (Hoechst):

The following chart represents a comparison of Hoechst's fraudulent price representations for its injectable form of the drug versus the truthful prices paid by the industry insider. It is [sic] also compares Hoechst's price representations for the tablet form of Anzemet and the insider's true prices. It is extremely interesting that Hoechst did not create a spread for its tablet form of Anzemet but only the injectable form. This is because Medicare reimburses Doctors for the injectable form of this drug and by giving them a profit, can influence prescribing. The tablet form is dispensed by pharmacists, who accept the Doctor's order. And this underscores the frustration that federal and state regulators have experienced in their attempts to estimate the truthful prices being paid by providers in the marketplace for prescription drugs and underscores the fact that, if we cannot rely upon the drug companies to make honest and truthful representations of their prices, Congress will be left with no alternative other than to legislate price controls.

NDC No:	Unit Size/ Type	Quantity	Net Price as Represented to Florida Medicaid	True Wholesale Price	Variance
0088-1206-32	100 mg/5 ml Injectable	1	\$124.90	\$70.00	Represented price 78% higher than true wholesale price.

(P007548-007588).

6. Additional Evidence Concerning Gammar

265. Similarly, Aventis increased AWPs for its Gammar product line to keep provider and intermediary reimbursement levels competitive with those created by the inflated AWPs of other manufacturers. A May 8, 1996 Aventis (Centeon) Interoffice Correspondence memo states:

Effective June 1, 1996, we will be revising our AVERAGE WHOLESALE PRICE for our Gammar P iv product line. We are implementing this change based on feedback from the field. Alpha and Bayer have recently increased their AWP pricing on

Gammimmune 10% and Venoglobulin S 10%. They are presently priced at \$75 and \$80 per gram respectively. . . . This change will help us maintain a competitive balance in the marketplace.

(ABAWP 004767) (Highly Confidential).

266. Centeon interoffice correspondence, dated June 23, 1999, reveals that a Centeon employee provided a representative of First Data Bank with the following information regarding Centeon's AWP for Gammar:

She asked me to validate Centeon's AWP and wholesale list price for Gammar PIV 5 and 10 gram vials.

I gave her the following info:

"Currently it is not Centeon's business practice to sell Gammar PIV to wholesalers. But should a wholesaler place an order, our wholesale list price is \$52/gram, or \$260 for 5 gram vial, and \$520 for 10 gram vial."

"Centeon's suggested AWP is \$400 for 5 gram vial, and \$800 for 10 gram vial. This is pricing as reported to First Data Bank, but we do not sell product at these prices."

(ABAWP 005315) (Highly Confidential).

267. U.S. Rep. Thomas J. Bliley, in a May 4, 2000 letter to the CEO of Aventis (Behring), also stated concerns regarding Aventis' pricing of Gammar:

The Office of Inspector General (OIG) at the Department of Health and Human Services determined that the Medicare-allowed amount for immune globulin, a pharmaceutical product sold by your company under the name Gammar, in Fiscal Year 1996 was \$42.21. The OIG further estimated that the actual wholesale price of this drug was \$16.12 and the highest available wholesale price that the OIG was able to identify was \$32.11.

(P006962-P006966)

7. Inflated AWPs From Aventis' Price Lists

268. In response to government subpoenas, Aventis produced numerous price lists setting forth spreads between AWPs and prices offered to wholesalers, providers and other

intermediaries. A review of those price lists reveals that Aventis has consistently offered drugs and other solutions to its customers at prices significantly below the published AWP and that the spread was of great importance to its customers. To repeat every one of those drugs and the spread offered to each specific customer here is not practical.

269. A March 4, 1997 price list issued by Arcola Laboratories (a division of Rhonel-Poulenc Rorer Pharmaceuticals sets the AWP for Calcimar (calcitonin-salmon) at \$31.35, with a cost of \$12.00 – for a spread of 161%. (AV-AAA-000705).

270. As set forth above, Aventis' scheme to inflate its reported AWPs and market the resulting spread to increase the market share of its drugs has resulted in excessive overpayments by Plaintiffs and the Class.

8. Aventis Concealed its AWP Manipulation

271. Aventis deliberately acted to conceal its fraudulent reporting and marketing of the AWP spread. For example, in response to a May 26, 1995 fax request from *Red Book*, Aventis refused to provide Wholesale Acquisition Cost (WAC) for products it listed in the *Red Book* database – in spite of *Red Book*'s assurances that WAC information would be distributed via electronic means only. (ABA WP 008420) (Highly Confidential). Aventis effectively hid the AWP spread from Plaintiffs and the Class.

E. Baxter

272. Baxter engages in an organization-wide and deliberate scheme to inflate AWPs. Baxter has stated fraudulent AWPs for all or almost all of its drugs those set forth below. The specific drugs of Baxter for which relief is sought in this case are set forth in Appendix A and are summarized below:

Manufacturer	Brand Name (if applicable)	Generic Name	Therapeutic Category/Usage
BAXTER	Aggrastat	tirofiban hydrochloride	Glycoprotein Receptor Inhibitor (Blood Modifier) Used in the treatment of acute coronary symptoms
	Ativan	lorazepam	Antianxiety Agent (Psychotherapeutic Agent); Anticonvulsant Used to relieve anxiety and treat insomnia
	Bebulin VH	factor ix (systemic)	Antihemorrhagic Agent Used to treat hemophilia B
	Brevibloc	esmolol hcl	Autonomic Nervous System Agent Used in the treatment of tachyarrhythmias in critical situations
	Buminate	albumin (human)	Plasma Fraction (Blood Modifier) Used in the treatment of hypovolemia and hypoalbuminemia
	Claforan	cephalosporin (systemic)	Antibacterial Agent (Anti-Infective Agent) Used in the treatment of infections caused by bacteria
	Gammagard S/D	immune globulin solution	Antibacterial Agent (Anti-Infective Agent) Used to prevent or treat some illnesses.
	Gentran	dextran	Blood Derivative; Blood Modifier Used in the emergency treatment of shock
	Holoxan/Iflex	ifosfamide	Antineoplastic Used in the treatment of various forms of cancer
	Iveegam EN	immune globulin iv	Antibacterial Agent (Anti-Infective Agent) Used as replacement therapy in patients with primary immunodeficiency syndromes
	Osmitol	mannitol	Osmotic Diuretic Used to promote diureses during treatment of acute kidney failure. Also used to reduce intraocular and intracranial pressure
	Recombinate	factor viii	Antihemophilic Factor Used to induce blood clotting
	Travasol	amino acid	Dietary Supplement Used for nutritional support in cancer patients
	Vancocin HCl	vancomycin hydrochloride	Antibacterial Agent (Anti-Infective Agent) Used in the treatment of infections caused by bacteria
		cisplatin	Antineoplastic Used to treat cancer of the bladder, ovaries, and testicles
		dextrose	Caloric Agent; Electrolyte Replenisher Used to increase intake of calories and fluids

Manufacturer	Brand Name (if applicable)	Generic Name	Therapeutic Category/Usage
		doxorubicin hcl	Antineoplastic Used in the treatment of various forms of cancer
		gentamicin	Antibacterial Agent (Anti-Infective Agent) Used to treat serious bacterial infections
		heparin	Anticoagulant (Cardiovascular Agent) Used to decrease the clotting ability of the blood
		sodium chloride	Flush; Abortifacient Used to remove medicine and blockage from intravenous (IV) catheter. Also used to induce abortion

1. Baxter Has Been the Target of Government Investigations

273. Baxter has been investigated by the United States Department of Justice, Department of Health and Human Services Office of Inspector General, the Attorney General for the State of California, the Attorney General for the State of Texas, the Attorney General for the State of Illinois, and the Committee on Commerce of the House of Representatives.

274. These investigations confirm that Baxter has engaged in a deliberate scheme to inflate AWPs for many or most of its drugs. A Baxter document made public as a result of the congressional investigation entitled, “Confidential – Baxter Internal Use Only,” acknowledged that: “Increasing AWPs was a large part of our negotiations with the large homecare companies.” Baxter further admitted in internal documents that homecare companies that reimburse based on AWP make a significantly higher margin. Thus, Baxter’s own documents demonstrate its active participation in the scheme to artificially inflate AWPs.

1. Baxter’s Definition and Understanding of AWP

275. Despite its manipulation, Baxter understood what AWP should mean: “The average price that a pharmacy (or provider) pays for the product from their drug wholesaler or distributor.” (BAX MDL 0011378) (Highly Confidential). Contrary to its own definition of

AWP, Baxter nonetheless set AWPs for its drugs far in excess of what providers paid for those drugs.

2. Baxter Controls the Published AWP for its Products

276. Baxter has controlled and set the AWPs for its pharmaceutical products through direct communications with industry compendia during the Class Period. For example, a September 7, 1995 inter-office memorandum provides:

I have been in contact with both *Red Book* and Medispan earlier this year about our AWPs. I told them that we will not be raising our AWPs for FVIII in 1995, and will only increase IGIV in the event of a label change. There are a few general rules about AWP adjustments.

- A manufacturer may raise AWPs at any time in the year. There is a monthly publication called the *Red Book* Update that lists all changes to the April publication (the big red book).
- If a manufacturer does decide to increase AWPs: - payors want a justification for the increase. This is why we typically don't increase the AWP unless we have a label change, product enhancement

(BAX MDL 0004754) (Highly Confidential).

3. Baxter's AWP Manipulation Benefited Providers at the Expense of the Class

277. In at least one internal document, Baxter recognized that deliberate manipulation of the spread was being wrongly used to gain competitive advantage by manufacturers:

The deliberate manipulation of AWP or WAC prices is a problem that we need to address. The spread between acquisition cost and AWP/WAC is direct profit for customers, and is being used to increase product positioning in the market by certain manufacturers.

(BAX MDL 0012778) (Highly Confidential) (emphasis added).

278. Despite this recognition, Baxter nonetheless continued to manipulate its AWPs in order to maintain the competitiveness of its own products based upon the spread. In a January 6,

1992 inter-office memorandum, Baxter informs its employees how to respond to inquiries concerning AWP increases for Baxter products:

If you receive inquiries from customers or payors questioning our rationale on this recent increase in Published AWP for Baxter products please communicate the following message and no more.

If any further information is needed please send the inquiry to me directly.

A recent review of industry published direct prices and AWPs revealed that Baxter's published AWPs are significantly lower than competitive AWPs. We have therefore adjusted our AWPs to meet competitive levels.

Most of Baxter General Healthcare Division's products are sold to distributors at negotiated contract prices that are different from AWPs. We do not have knowledge of or input to the actual prices charged to the provider by our distributors. The contracted prices to our distributors will not be directly affected by this change in AWPs.

(BAX MDL 0004210) (Highly Confidential).

279. In addition, Baxter's marketing and sales documents, which were prepared and disseminated to its employees and agents via the U.S. mail and interstate wire facilities, compared the costs of their respective drugs to those of their respective competitors and were intended to induce physicians to use Baxter drugs and shift market share in its favor. Other documents created and disseminated by Baxter compared the AWP and the actual "cost" of their respective drugs, so that medical providers could easily see the different "return-to-practice" amounts available for different levels of purchase.

4. Specific Baxter AWPs Documented by the DOJ

280. In a report published by the DHHS (AB-00-86), the DOJ documented at least 41 instances where the published AWPs for various dosages of drugs manufactured by Baxter were substantially higher than the actual prices listed by wholesalers. The chart below sets forth the four drugs identified by the DOJ and the spread associated with one particular dosage of each drug. These figures compare the DOJ's determination of an accurate AWP for that particular

dosage, based upon wholesalers' price lists, with the AWP reported by Baxter in the 2001 *Red Book*.

Drug in Lowest Dosage Form	Baxter's 2001 Red Book AWP	DOJ Determined Actual AWP	Difference	Percentage Spread
Dextrose	\$928.51	\$2.25	\$926.26	41,167%
Dextrose Sodium Chloride	\$357.69	\$2.93	\$354.76	12,108%
Sodium Chloride	\$928.51	\$1.71	\$926.80	54,199%
Factor VIII	\$1.28	\$.92	\$.36	39%

(P006299-006316).

5. Evidence Concerning Gammagard S/D (immune globulin solution)

281. Baxter admittedly manipulated the AWP for Gammagard S/D. In 1996, Baxter distributed a memo providing “[t]he deliberate manipulation of AWP or WAC prices is a problem that we need to address. The spread between acquisition cost and AWP/WAC is a direct profit for customers, and is being used to increase product positioning in the market by certain manufacturers.” Immediately below this text is a handwritten note reading “[w]ill raise AWP for GG/SD by 15%.” (BAX MDL 0012778) (Highly Confidential).

282. According to Baxter's own documents, the published AWPs for Gammagard S/D were higher than the actual prices provided to wholesalers. In a customer announcement dated September 24, 1996, Baxter increased the AWP for one particular dosage of Gammagard S/D from \$640.71 to \$737.00, and the WAC from \$365.00 to \$420.00. The difference between the new AWP and the new WAC (\$317.00) constituted a 43% spread. (BAX MDL 005366) (Highly Confidential).

6. Inflated AWPs From Baxter's Price Lists

283. In response to government subpoenas, Baxter produced numerous price lists setting forth spreads between AWPs and prices apparently offered to wholesalers, providers and other intermediaries. A review of those price lists reveals that Baxter has consistently offered hundreds of its drugs and other solutions to its customers at prices significantly below the

published AWP and that the spread was of great importance to its customers. To repeat every one of those drugs and the spread offered to each specific customer here is not practical. However, set forth below in Tables 1 and 2 are a number of those drugs (not already referenced above) with spreads between the AWPs and direct prices. Table 1 is an analysis of certain dosages of Baxter drugs from a document entitled "Baxter Healthcare Corporation Intravenous and Irrigation Solution Products Report" (BAX MDL 0003428-46) (Highly Confidential)).

Table 1

Drug	AWP	DP	Difference	% Spread
Ringers	10.84	6.34	4.50	71%
Lactated Ringers	12.36	7.43	4.93	66%
Plasma-lyte 148	15.67	10.85	4.82	44%
5% Travert and electrolyte no. 2	16.39	11.30	5.09	45%
6% Gentran75	73.46	33.19	40.27	121%
Sterile Water	9.97	6.15	3.82	62%
Sodium Lactate	17.98	11.11	6.87	62%
Osmitol	70.28	35.12	35.16	100%
Gentamycin	10.78	7.25	3.53	49%
Metronidazole injection	15.34	7.85	7.49	95%
Rocephin	40.18	32.67	7.51	23%
Nitroglycerin	17.37	9.82	7.55	77%
Potassium Chloride Injection	14.63	10.16	4.47	44%
Dopamine	19.30	13.40	5.90	44%
Lidocaine	22.74	13.48	9.26	67%
Heparin	9.94	6.49	3.45	53%
Theophylline	11.45	7.81	3.64	47%
Glycine for Irrigation	32.87	19.70	13.17	67%
Tis-U-Sol	22.73	11.36	11.37	100%
Acetic Acid	20.70	10.91	9.79	90%
Irrigating Solution G	16.67	11.04	5.63	51%
Balanced Salt Solution	28.76	15.00	13.76	92%
Sodium Bicarbonate	39.23	16.36	22.87	140%

284. Table 2 is an analysis of certain dosages of Baxter drugs from a document entitled "IV Nutrition Products" (BAX MDL 0003421-26) (Highly Confidential).

Table 2

Drug	AWP	DP	Difference	% Spread
Novamine Injection	95.14	51.48	43.66	85%
Travasol	83.44	40.21	43.23	108%
RenAmin Injection	75.00	48.00	27.00	56%

Aminess Essential Amino Acid	107.35	66.00	41.35	63%
BranchAmin Injection	93.60	60.00	33.60	56%

7. Baxter Provided Free Goods and Other Incentives

13. Baxter also provided physicians with free goods with the understanding that physicians would bill for those goods, in violation of federal law. Billing for free goods was a way for physicians to obtain greater profit at the expense of the Class. Baxter's fraudulent use of free goods aimed at increasing market share is evidenced by an internal memorandum from a Baxter contract administrator to certain field sales managers encouraging the distribution by U.S. mail or otherwise of free product to achieve overall price reduction:

BAXTER: "The attached notice from Quantum Headquarters was sent on April 10th to all their centers regarding the reduction on Recombinate pricing. Please note that they want to continue to be invoiced at the \$.81 price. They have requested that we send them free product every quarter calculated by looking at the number of units purchased in that quarter and the \$.13 reduction in price . . . free product given to achieve overall price reduction."

Letter from Stark, Committee on Ways and Means to Holman, Pres. Pharmaceutical Research and Manufacturers of America, Sept. 28, 2002 (P0075410-44).

285. As set forth above, Baxter's scheme to inflate its reported AWPs, market the resulting spread, and channel to providers "free" goods – all in order to increase the market share of its drugs – has resulted in excessive overpayments by Plaintiffs and the Class.

F. Bayer

286. Bayer engages in an organization-wide and deliberate scheme to inflate AWPs. Bayer has stated fraudulent AWPs for all or almost all of its drugs, including those set forth below. The specific drugs of Bayer for which relief is sought in this case are set forth in Appendix A, and are set forth below:

Manufacturer	Brand Name (if applicable)	Generic Name	Therapeutic Category/Usage
BAYER	Cipro	ciprofloxacin or ciprofloxacin hcl	Antibiotic Agent (Anti-Infective Agent) Used in the treatment of various bacterial infections, including anthrax
	Cipro XR	ciprofloxacin hcl-ciprofloxacin betaine	Antibiotic Agent (Anti-Infective Agent) Used in the treatment of various bacterial infections, including anthrax
	DTIC-Dome	dacarbazine	Antineoplastic Used in the treatment of melanoma and Hodgkin's disease
	Gamimune N	immune globulin (human) iv	Immunizing Agent Used as maintenance therapy in patients with compromised immune systems
	Koate-HP	antihemophilic factor (human)	Antihemophilic Factor (Blood Modifier) Used to increase blood clotting and decrease bleeding episodes
	Kogenate	antihemophilic factor (recombinant)	Antihemophilic Factor (Blood Modifier) Used to increase blood clotting and decrease bleeding episodes
	Mithracin	plicamycin	Antineoplastic; Antihypercalcemic Agent Used in the treatment of various forms of cancer

1. Bayer Has Been the Target of Government Investigations

287. In connection with its scheme to inflate AWPs, Bayer has been investigated by the Department of Justice, Department of Health and Human Services, Office of Inspector General, and the Commonwealth of Massachusetts. Bayer agreed to settle claims asserted by the United States government and 47 states arising from its fraudulent pricing and marketing practices. According to the DOJ's January 23, 2001 press release:

The government's investigation of the allegations...revealed that [Bayer] beginning in the early 1990s, falsely inflated the reported drug prices – referred to by the industry as the Average Wholesale Price (AWP), the Direct Price and the Wholesale Acquisition Cost – used by state governments to set reimbursement rates for the Medicaid program. By setting an extremely high AWP and, subsequently, selling drugs at a dramatic discount, Bayer induced physicians to purchase its products rather than those of competitors by enabling doctors to profit tremendously from reimbursement paid to them by the government.

The Bayer AWPs at issue in the investigation involved Bayer's biologic products such as Kogenate, Koate-HP, and Gamimmune, which are widely used in treating hemophilia and immune deficiency diseases. The investigation further revealed that the practice in which Bayer selectively engaged, commonly referred to as "marketing the spread," also had the effect of causing other drug companies to inflate their AWPs.

"Bayer Corporation Settlement on Medicaid Drug Pries" (P011236-011237).

288. As part of its settlement of government claims in 2000, Bayer is required, under the terms of a corporate integrity agreement, to provide state governments and the federal government with the average selling prices of its drugs – a price which accounts for all discounts, free samples, rebates and all other price concessions provided by Bayer to any relevant purchaser that result in a reduction of the ultimate cost to Bayer's customers.

289. In April 2003, Bayer also agreed to pay the government \$251.6 million in civil penalties for violating the Federal Prescription Drug Marketing Act for alleged overcharges involving its antibiotic Cipro and its high blood pressure drug Adalat.

1. Bayer Controls the Published AWP for Its Products

290. Bayer has controlled and set the AWPs for its pharmaceutical products through direct communications with industry compendia during the Class Period. In one internal marketing memorandum, Bayer stated:

I would like to formally request that you contact Redbook and request an AWP change for all sizes (670-20, 670-30, 670-50) of Kogenate from \$1.18 per IU to \$1.24 per IU to match Baxter's increase. I have attached a letter from Baxter to Redbook outlining their price change request. (Prior to making the change in AWP for Kogenate, please confirm with Redbook that Baxter has indeed initiated a price change.)

(BAY005278) (Highly Confidential).

2. Bayer's AWP Manipulation Benefited Providers at the Expense of the Class

291. As detailed in a September 28, 2000 letter from Representative Stark to Alan F. Holmer, President of the Pharmaceutical Research and Manufacturers of America, internal Bayer

documents reveal Bayer knowingly participated and directed the scheme to artificially inflate the AWPs for its products and to market the spread:

BAYER: "Chris, if Baxter has increased their AWP then we must do the same. Many of the Homecare companies are paid based on a discount from AWP. If we are lowed [sic] than Baxter then the return will be lower to the HHC. It is a very simple process to increase our AWP, and can be done overnight."

(P007549.)

292. Tom Bliley, in a letter dated September 25, 2000 to the Health Care Financing Administration, analyzed drug sales in Florida and noted that sales of Bayer's WhinRho "skyrocketed" when competitors reduced their spreads but Bayer did not.

3. Specific Bayer AWPs Documented by the DOJ

293. In a report published by the DHHS, the DOJ documented at least 10 instances where the published AWPs for various dosages of two drugs manufactured by Bayer were substantially higher than the actual prices listed by wholesalers. The chart below sets forth the two drugs identified by the DOJ and the spread associated with one particular dosage of each drug. These figures compare the DOJ's determination of an accurate AWP for that particular dosage, based upon wholesalers' price lists, with the AWP reported by Abbott in the 2001 *Red Book*.

Drug	Bayer's 2001 Red Book AWP	DOJ Determined Actual AWP	Difference	Percentage Spread
Immune Globulin	\$450.00	\$362.50	\$87.50	24%
Factor VIII	\$0.92	\$0.42	\$0.50	119%

(AB-00-86 (P006299-006316)).

294. In a DHHS OIG report (*see* OEI-03-00-00310 (P006398-006424)), the government also discovered that the AWP for all immune globulin pharmaceuticals (of a dosage of 5g), including Bayer's Gammimune® (Bayer was one of five manufacturers of the dosage listed in the 1997 *Red Book*), were over inflated by an average spread of 32.21%.

295. According to the government's settlement with Bayer arising out of Bayer's fraudulent pricing and marketing practices, the Bayer AWPs at issue in the investigation (and ultimately settled) include the AWPs for Kogenate.

4. Inflated AWPs From Bayer's Price Lists

296. According to Bayer's own documents, the published AWPs for its drugs were higher than the actual prices provided to wholesalers. In response to government subpoenas, Bayer produced numerous price lists setting forth spreads between AWPs and prices apparently offered to wholesalers, providers and other intermediaries. A review of those price lists reveals that Bayer has consistently offered hundreds of its drugs and other solutions to its customers at prices significantly below the published AWP and that the spread was of great importance to its customers.

5. Bayer Provided Free Goods and Other Incentives

297. In addition to marketing the spread, Bayer has utilized other impermissible inducements to stimulate sales of its drugs. These inducements were designed to result in a lower net cost to the provider while concealing the actual wholesale price beneath a high invoice price. By utilizing "off-invoice" inducements, Bayer provided purchasers with substantial discounts meant to gain their patronage while maintaining the fiction of a higher wholesale price.

298. Evidence of these practices is found in an October 1, 1996 Bayer internal memorandum addressing volume sales opportunities for the pharmaceutical Kogenate®:

BAYER: "I have been told that our present Kogenate price, \$.66 is the highest price that Quantum is paying for recombinant factor VIII. In order to sell the additional 12mm/u we will need a lower price. I suggest a price of \$.60 to \$.62 to secure this volume. From Quantum's stand [sic] point, a price off invoice, is the most desirable. We could calculate our offer in the form of a marketing grant, a special educational grant, payment for specific data gathering regarding Hemophilia treatment, or anything else that will produce the same dollar benefit to Quantum Health Resources."

299. As set forth above, Bayer's scheme to inflate its reported AWPs and market the resulting spread to increase the market share of its drugs and its use of other "off invoice" rebates and financial inducements to its customers has resulted in excessive overpayments by Plaintiffs and the Class.

300. Bayer routinely offered its customers off-invoice discounts as one feature of its standard contracts. (BAYM002428).

6. Bayer Concealed Its AWP Manipulation

301. Bayer deliberately acted to conceal its fraudulent reporting and marketing of the AWP spread. Bayer routinely required that its customers keep secret the prices they were being charged for Bayer drugs. (BAYM000913, BAYM002436).

G. The Boehringer Group

302. The Boehringer Group engages in an organization-wide and deliberate scheme to inflate AWPs. The Boehringer Group has stated fraudulent AWPs for all or almost all of its drugs, including those set forth below. The specific drugs of The Boehringer Group for which relief is sought in this case are set forth in Appendix A and are identified below:

Manufacturer	Brand Name (if applicable)	Generic Name	Therapeutic Category/Usage
BOEHRINGER GROUP (Boehringer, Ben Venue, Bedford and Roxane)	Viramune	nevirapine	Antiviral Agent (Anti-Infective Agent) Used in the treatment of HIV infection
		acyclovir sodium	Anti-Infective Agent Used in the treatment of herpes infections
		amikacin sulfate	Antibiotic Agent (Anti-Infective Agent) Used to treat respiratory tract, urinary tract, bone, skin and soft tissue infections
		cytarabine	Antineoplastic Used to treat leukemia and non-Hodgkin's lymphoma
		doxorubicin hydrochloride	Antineoplastic Used in the treatment of ovarian cancer and AIDS-related Kaposi's sarcoma

Manufacturer	Brand Name (if applicable)	Generic Name	Therapeutic Category/Usage
		etoposide	Mitotic Inhibitor (Antineoplastic) Used in the treatment of testicular neoplasm and small cell cancer of the lung
		leucovorin calcium	Antianemic Agent (Blood Modifier) Used in the treatment of anemia
		methotrexate sodium	Antineoplastic Used in the treatment of various forms of cancer
		mitomycin	Antineoplastic Used in the treatment of various forms of cancer
		vinblastine	Antineoplastic Used in the treatment of various forms of cancer, including lymphoma and breast cancer
		vinblastine sulfate	Antineoplastic Used in the treatment of various forms of cancer, including lymphoma and breast cancer

1. The Boehringer Group Has Been the Target of Government Investigations

303. In connection with its scheme to inflate AWPs, The Boehringer Group has been investigated by the Department of Justice, the Department of Health and Human Services Office of Inspector General, the Committee on Commerce of the House of Representatives, and the Nevada Attorney General.

1. The Boehringer Group Controls the Published AWP for Its Products

304. The Boehringer Group has controlled and set the AWPs for its pharmaceutical products through direct communications with industry compendia during the Class Period. For example, a September 27, 1996 document entitled "*Red Book* Product Listing Verification" required Defendant to sign each page that contained a list of The Boehringer Group's products, NDC numbers, AWPs, WACs and price effective dates. (MDL BV 000799). Similarly, a *Red Book* New Product Information Form dated November 25, 1996 was completed by Bedford for

the drug Ketamine Hydrochloride Injection USP and required Bedford to fill in the AWP and WAC for the product (which it did). (MDL BV 000807).

305. Despite its actual verification of the AWPs in the *Red Book*, The Boehringer Group claims that it does not set “AWPs” but nonetheless agrees that the “terms ‘average’ and ‘wholesale’ are the standard dictionary definitions.” In a letter dated August 20, 1999 to the Chairman of the Committee on Commerce regarding “Response to Request for Pricing Information, July 19, 1999” (“Bedford’s AWP Response”), counsel for Bedford Laboratories stated as follows:

Please provide all definitions of AWP used by your company since January 1, 1996 for the purpose of determining the reimbursement price for Medicare-covered drugs, and all records relating to those definitions. In particular, please provide the specific definitions you apply to the terms “average” and “wholesale.”

Answer: The term “AWP”, which we interpret as meaning Average Wholesale Price, is not used by Bedford Laboratories in pricing any of its products. Moreover, Bedford has not and does not take into account the “reimbursement price for Medicare-covered drugs” in pricing any of its products. Rather than use AWP, Bedford established a Hospital Price List for its products. The Hospital Price List refers to the price a customer without a contract, who is not a wholesaler or distributor, would pay for Bedford’s products. It also refers to a suggested price that a wholesaler charges its customers. This terminology is used because the majority of Bedford’s customers, particularly for drugs such as Leucovorin, are hospitals.

The pharmaceutical reporting services, such as Redbook, independently identify Bedford’s Hospital Price List as AWP. The prices Bedford charges its wholesale customers are referred to at Bedford as Wholesale Price Lists, which are identical for all of Bedford’s wholesale customers. These prices are identified by the pharmaceutical reporting services as Wholesale Acquisition Cost (“WAC”). *Given its pricing terminology and practices, Bedford’s definitions of the terms “average” and “wholesale” are the standard dictionary definitions.”*

(MDL BV 001941-1944, at 1941-1942) (Confidential) (emphasis added).

306. Notwithstanding its attempt to distance itself from its published AWPs, The Boehringer Group effectively ratified the AWPs set by its predecessors. In Bedford's AWP Response, counsel responded:

. . . Bedford performs no AWP calculation for Leucovorin, 50 mg and did not do so during calendar year 1998. . . . This price was established by Chiron Therapeutics, which prior to May, 1996, had the marketing responsibilities for this product. Bedford took over those responsibilities in May of 1996 and continued the price established by Chiron. Prior to that time, Ben Venue, Bedford's parent, only manufactured this product. For that reason, Bedford is not aware of how Chiron originally priced this product.

(MDL BV 001941-1944, at 1942) (Confidential) (emphasis added).

307. Of course, depending on which government entity was performing the investigation and the date of the government's inquiries, The Boehringer Group's "definition" of AWP changed. By November 2, 1999, Bedford told the Committee on Commerce that it understood AWP to be tied to "the manufacturer's suggested prices to customers of its customers." (MDL BV 006761-65, at 6763).

308. In a letter dated June 5, 2000 to the Nevada Attorney General regarding the Attorney General's inquiries about Bedford's AWP, Bedford responded in pertinent part:

1. Identify what Bedford represents to be its understanding of the meaning "AWP."

Answer: Bedford's understanding of AWP, derived from its experience in the industry, is that it is a suggested price identified by pharmaceutical companies as the price a wholesaler may wish to charge its customers for pharmaceutical products. Bedford has always viewed AWP as a suggested 'retail' price to the customers of wholesalers and not as an acquisition cost to wholesalers.

2. Does Bedford report AWP to First Databank for all its products? With what frequency? How is that information communicated?

Answer: Bedford does not use the term AWP in its business, *except as a semantical concession* to those who, like the price reporting services, have reported Bedford's Hospital List Price ("HLP") as an AWP. Upon request by FDB, Bedford provides its

price lists, which consist of the HLPs and Wholesale List Prices (“WLPs”) for its products. ****

Bedford reports this information, usually by facsimile, at least once a year, and more frequently upon request by FDB.

(MDL BV 002071-73, at 2072) (Confidential) (emphasis added).

309. In fact, even armed with the knowledge that industry compendia use Bedford’s HLPs as AWPs, Bedford admits that HLPs do not accurately reflect the AWP for its drugs:

As indicated above, Bedford does not communicate AWPs for its products. However, it is aware that pharmaceutical price reporting services have chosen to report Bedford’s HLP as AWP. Bedford has always reported its HLP accurately. *These list prices are not averages of the wholesale prices for Bedford’s products.*

(MDL BV 002071-73, at 2073) (emphasis added).

310. In practice, Bedford did in fact acknowledge that its HLPs should be used as AWPs in the industry compendia. For example, a June 17, 1996 fax cover sheet from Bedford to Medispan states: “[S]ee corrections noted for select products on the AWP cost!” (MDL BV 000770) (Confidential). Attached to this cover sheet is Bedford’s Hospital Price List dated May 1, 1996 in which certain prices are crossed out and replaced with typewritten prices. (MDL BV 000771-780) (Confidential). Similar cover sheets with the same notation and the same price lists were also sent to First Data Bank (MDL BV 000774-780, MDL BV 000781-785) (Confidential) (“[S]ee corrections made on select products for the AWP!”) and *Red Book* (MDL BV 000793-95) (Confidential) (“Corrections made on the AWP for select products!”).

2. Specific Boehringer AWPs Documented by the DOJ

311. In a report published by the DHHS, the DOJ documented at least 32 instances where the published AWPs for various dosages of nine drugs manufactured by The Boehringer Group were substantially higher than the actual prices listed by wholesalers. The chart below sets forth the nine drugs identified by the DOJ and the spread associated with one particular dosage of each drug. These figures compare the DOJ’s determination of an accurate AWP for

that particular dosage, based upon wholesalers' price lists, with the AWP reported by The Boehringer Group in the 2001 *Red Book*.

Drug	The Boehringer Group's 2001 <i>Red Book</i> AWP	DOJ Determined Actual AWP	Difference	Percentage Spread
Acyclovir Sodium	\$ 528.00	\$ 207.00	\$ 321.00	155%
Amikacin Sulfate	\$ 437.50	\$ 65.33	\$ 372.17	570%
Mitomycin	\$ 128.05	\$ 51.83	\$ 76.22	147%
Cytarabine	\$ 62.50	\$ 3.55	\$ 58.95	1,661%
Doxorubicin HCL	\$ 945.98	\$ 139.75	\$ 806.23	577%
Etoposide	\$ 110.00	\$ 8.45	\$ 101.55	1,202%
Leucovorin Calcium	\$ 184.40	\$ 2.76	\$ 181.64	6,581%
Methotrexate Sodium	\$ 68.80	\$ 2.63	\$ 66.17	2,516%
Vinblastine Sulfate	\$ 212.50	\$ 8.19	\$ 204.31	2,495%

3. Inflated Boehringer Group AWPs From Bedford's Price Lists

312. According to Bedford's own documents, the published AWPs for the drugs listed above by the DOJ were, in fact, higher than the actual prices provided to wholesalers. In response to government subpoenas, Bedford produced several price lists setting forth spreads between AWPs and prices apparently offered to wholesalers, providers and other intermediaries. A review of those price lists reveals that Bedford has consistently offered the above drugs and other solutions to its customers at prices significantly below the published AWP and that the spread was of great importance to its customers. (MDL BV 000799-806).

313. As set forth above, The Boehringer Group's scheme to inflate its reported AWPs and market the resulting spread to increase the market share of its drugs has resulted in excessive overpayments by Plaintiffs and the Class.

H. B. Braun

314. B. Braun engages in an organization-wide and deliberate scheme to inflate AWPs. B. Braun has stated fraudulent AWPs for all or almost all of its drugs, including those set forth

below. The specific drugs of B. Braun for which relief is sought in this case are set forth in Appendix A and identified below:

Manufacturer	Brand Name (if applicable)	Generic Name	Therapeutic Category/Usage
B. BRAUN		dextrose	Caloric Agent; Electrolyte Replenisher Used to increase intake of calories and fluids
		dextrose in lactated ringers	Caloric Agent; Electrolyte Replenisher Used to increase intake of calories and fluids
		dextrose w/ sodium chloride	Caloric Agent; Electrolyte Replenisher Used to increase intake of calories and fluids
		heparin sodium (porcine) in d5w	Blood Modifier Used to treat and prevent thrombosis and pulmonary embolism
		sodium chloride	Flush; Abortifacient Used to remove medicine and blockage from intravenous (IV) catheter. Also used to induce abortion
		sodium chloride (gu irrigant)	Flush; Abortifacient Used to remove medicine and blockage from intravenous (IV) catheter. Also used to induce abortion

1. B. Braun Has Been the Target of Government Investigations

315. In connection with its scheme to inflate AWPs, B. Braun has been investigated by the United States Department of Justice, the Office of Inspector General of the Department of Health and Human Services, the Attorney General for the State of Texas, and the Attorney General for the State of California.

1. B. Braun's Understanding of AWP

316. Undated notes made in conjunction with a meeting held to address a customer's concerns about B. Braun's decision to increase AWPs for a number of drugs reveals B. Braun's understanding of AWPs:

Let Rob know that most products are already (AWPs) above wholesaler prices. Make him understand that AWPs are based on not what prices they buy it at but at what price they . . . This

doesn't matter as for as setting AWPs it is not what the wholesaler sells the products for that set the AWP price (average sell prices).

B. Braun's documents prove that it knew that customers – and members of the Class – understood AWPs to be related to average wholesale prices. (BBMDL 001907) (Highly Confidential).

2. B. Braun Controls the Published AWP for Its Products

317. B. Braun has controlled and set the AWPs for its pharmaceutical products through direct communications with industry compendia during the Class Period.

a. A September 11, 1995 McGaw (acquired by B. Braun in 1997) internal memorandum addresses the company's recognition of its ability to control the published AWP:

Below I have listed all data base companies the specific percentage mark-up that they apply to our "list" prices:

First Data Bank	20%
Medispan	25%
Redbook	Whatever we want them to publish
Facts & Comparisons	Information on our products should be submitted to this company although they do not publish pricing, only clinical data

Connie, when we submit our list and AWP prices to these companies this year, let's submit a mark-up of 25% above our list prices to all companies so it will be consistent.

(BBMDL 000013) (Highly Confidential).

b. Notes from an October 1994 telephone conversation between a representative of *Red Book* and McGaw provide further proof that B. Braun understood it could unilaterally control its AWPs:

Spoke to Roni Lane at Redbook. She did not know why Baxter not listed in OTC section. She said we can send her whatever price for AWP we want and she will have it published.[] If we increase AWP prices we can send her only AWP to have published ad not list so spread between the 2 won't show. No one regulates pricing

this is up to the mfg. Co. and it is option that mfg. Publish theirs, not a requirement.

(BBMDL 013372) (Highly Confidential).

3. B. Braun's AWP Manipulation Benefited Providers at the Expense of the Class

318. The purpose of B. Braun's manipulation was to increase the spread in order to maximize the profit to providers and other intermediaries at the expense of Plaintiffs and the Class. Braun understood, as reflected in a June 15, 1992 memorandum, that a higher AWP was "advantageous with payors who reimburse based on a cost plus arrangement." (BBMDL 008056) (Highly Confidential).

319. As evidenced by a September 18, 1996 e-mail, B. Braun recognized that manipulating AWPs to meet its competitors was "scandalous," "unethical" and "fraudulent":

I'm writing to you because of a potential problem for McGaw and a potentially larger problem for IVAX. It has to do with the method in which products are sold in our industry at a low actual price, and the wholesaler (our customer) bills Medicare for an arbitrary "average wholesale price." These prices are published in compendia such as Red Book and Blue Book.

I'm wondering if you saw the article in *Barron's* on June 10, 1996. This issue is described in great detail including the fact that the Justice Department is looking into the issue and the Inspector General of Medicare is investigating these practices.

I have held up authorizing the continuation of this practice at McGaw for quite a few months, but they're most anxious to continue the process as our sales are suffering. According to the article, some say that it is not illegal, but it is unethical. I am concerned that McGaw will no sooner increase its average wholesale prices to meet its competitors when the entire industry is going to get slammed for what may be perceived as scandalous, or worse, fraudulent practice of reimbursement.

(BBMDL 000011) (Highly Confidential).

320. Despite discussing and memorializing its concerns, B. Braun promptly proceeded to manipulate its AWPs and market the spread in an effort to match the competition.

a. In an internal memorandum dated December 20, 1996, a B. Braun employee states:

I evaluated each McGaw AWP against Baxter's and Abbott's and individually determined which AWPs should be increased. . . . In general, I raised the McGaw AWPs to make them equivalent to Baxter.

(BBMDL 009658) (Highly Confidential).

b. A second memorandum, created in October of 1997 reveals that B. Braun subsequently performed an analysis to "assure that McGaw AWPs are in line with Baxter/Abbott AWPs on competitive products." (BBMDL 009763) (Highly Confidential). In fact, an October 17, 1997 B. Braun memorandum reveals that the company increased 54 separate AWPs following a review of 200 drugs to "make them equivalent to both Baxter and Abbott." (BBMDL 001891) (Highly Confidential). B. Braun increased the AWPs of 29 drugs in 1996 for the same reason. (BBMDL 009658) (Highly Confidential).

321. B. Braun, through its employees and agents, also provided free samples of its drugs, and purported educational grants, to providers. The free samples and educational grants would be used to offset the total cost associated with purchases of its drugs, thereby increasing the spread, while also concealing the actual cost of the drug from Plaintiffs and the Class.

322. In an October 30, 1998 memorandum addressing pricing strategies for its drug ProcalAmine, in lieu of a price reduction, B. Braun directs personnel to offer customers "something of value instead – for example, give them an educational grant, or sponsor a speaker[.]" The same memorandum also suggests that B. Braun employees might offer a "free case for every so many purchased" to match competitors' prices "without lowering" the price of its drug. (BBMDL 002088) (Highly Confidential).

4. Specific B. Braun AWPs Documented by the DOJ

323. In a report published by the DHHS (the "DHHS Report"), the DOJ documented at least 23 instances where the published AWPs for various dosages of 3 drugs manufactured by

B. Braun were substantially higher than the actual prices listed by wholesalers. The chart below sets forth the 3 drugs identified by the DOJ and the spread associated with one particular dosage of each drug. These figures compare the DOJ's determination of an accurate AWP for that particular dosage, based upon wholesalers' price lists, with the AWP reported by B. Braun in the 2001 *Red Book*.

Drug	B. Braun's 2001 <i>Red Book</i> AWP	DOJ Determined Actual AWP	Difference	Spread
Dextrose	\$11.28	\$1.61	\$9.67	601%
Dextrose Sodium Chloride	\$11.34	\$1.89	\$9.45	500%
Sodium Chloride	\$11.33	\$1.49	\$9.84	660%

5. Inflated AWPs From B. Braun Price Lists

324. In response to government subpoenas, B. Braun produced numerous price lists setting forth spreads between AWPs and prices offered to wholesalers, providers and other intermediaries. A review of those price lists reveals that B. Braun has consistently offered drugs and other solutions to its customers at prices significantly below the published AWP and that the spread was of great importance to its customers. To repeat every one of those drugs and the spread offered to each specific customer here is not practical. However, set forth below in Table 1 are a number of those drugs (not already referenced above) and the substantial spread offered to a particular B. Braun customer.

325. Table 1 is an analysis of certain dosages of B. Braun drugs from a document entitled "PHARMCO." (BBMDL 011831) (Highly Confidential)).

Table 1

Drug	Gerimed Unit Price	AWP	\$ Diff AWP	% Spread
Intralipid	\$6.75	\$57.87	\$51.12	757%
Lactated Ringers 1000	\$1.02	\$11.87	\$10.85	1063%
Travasol	\$6.05	\$82.34	\$76.29	1260%

326. As set forth above, B. Braun's scheme to inflate its reported AWPs and market the resulting spread to increase the market share of its drugs has resulted in excessive overpayments by Plaintiffs and the Class.

I. The BMS Group (Bristol-Myers, OTN and Apothecon)

327. The BMS Group has engaged in an ongoing deliberate scheme to inflate AWPs. The specific drugs for which relief is sought in this case are identified in Appendix A and are as follows:

Manufacturer	Brand Name (if applicable)	Generic Name	Therapeutic Category/Usage
BMS GROUP (Bristol-Myers, OTN and Apothecon)	Avapro	irbesartan	Antihypertensive Agent Used to treat hypertension
	Blenoxane	bleomycin sulfate	Antineoplastic Used in the treatment of various forms of cancer
	Buspar	buspirone hcl	Antianxiety Agent (Psychotherapeutic Agent) Used to treat certain anxiety disorders or to relieve the symptoms of anxiety
	Carboplatin	paraplatin	Antineoplastic Used to treat cancer of the ovaries
	Cefzil	cefprozil	Antibacterial Agent (Anti-Infective Agent) Used in the treatment of infections caused by bacteria
	Coumadin	warfarin sodium	Anticoagulant (Blood Modifier) Used to promote clotting
	Cytoxan	cyclophosphamide	Antineoplastic Used in the treatment of various forms of cancer
	Etopophos	etoposide phosphate	Antineoplastic Used to treat cancer of the testicles and certain types of lung cancer
	Glucophage	meformin hcl	Antihyperglycemic Agent Used to treat a type 2 diabetes mellitus.
	Monopril	flosinopril sodium	Antihypertensive Agent; Vasodilator (Cardiovascular Agent) Used to treat hypertension
	Monopril HCT	flosinopril sodium & hydrochloro-thiazide	ACE Inhibitor (Cardiovascular Agent) Used in the treatment of hypertension and congestive heart failure
	Plavix	clopidogrel bisulfate	Antithrombotic Agent Used to lessen the chance of heart attack or stroke

Manufacturer	Brand Name (if applicable)	Generic Name	Therapeutic Category/Usage
	Rubex	doxorubicin hcl	Antineoplastic Used in the treatment of various forms of cancer
	Serzone	nefazodone hcl	Antidepressant (Psychotherapeutic Agent) Used to treat mental depression
	Taxol	paclitaxel	Antineoplastic Used in the treatment of various forms of cancer
	Tequin	gatifloxacin	Antibacterial Agent (Anti-Infective Agent) Used to treat bacterial infections
	Vepesid	etoposide	Antineoplastic Used to treat cancer of the testicles and certain types of lung cancer
	Videx EC	didanosine	Antiviral Agent (Anti-Infective Agent) Used in the treatment of HIV infection
		amikacin sulfate	Antibiotic Agent (Anti-Infective Agent) Used to treat respiratory tract, urinary tract, bone, skin and soft tissue infections
		amphotericin b	Antifungal Agent (Anti-Infective Agent) Used to help the body overcome serious fungus infections

1. The BMS Group Has Been the Target of Government Investigations

328. In connection with its scheme to inflate AWPs, BMS has been investigated by the United States Department of Justice, Commonwealth of Massachusetts, Office of Inspector General of the U.S. Department of Health and Human Services, Attorney General for the State of Texas, State of California Department of Justice Office of the Attorney General, State of California Department of Justice, Bureau of Medi-Cal Fraud and Elder Abuse, and the U.S. House of Representatives, Committee on Commerce. Defendant Apothecon has been investigated in connection with its scheme to inflate AWPs by at least the Office of Medicare Fraud and Elder Abuse, Office of Attorney General, State of Texas.

329. These investigations confirm that BMS engaged in an ongoing deliberate scheme to inflate AWPs. For example, by letter dated February 27, 2001 to BMS, Rep. Stark outlined numerous examples of illegal practices by BMS. Referring to a letter from Denis Kaszuba, a

senior pricing analyst at BMS to Medispan, dated August 10, 1992 (BMSAWP/0011247), Rep.

Stark noted:

Bristol has control over the AWPs, DPs, and WACs published for its drugs and directs national publishers to change their prices. Bristol directed a national publisher of drug prices to increase all of Bristol's AWPs for oncology drugs by multiplying Bristol's supplied direct prices by a 25% factor rather than the previous 20.5% factor . . . The increase in the AWP created a spread that, in itself, provided a financial kickback to oncologists for prescribing Bristol's cancer drugs.

330. In the same letter, Rep. Stark noted:

The evidence clearly shows that Bristol has intentionally reported inflated prices and has engaged in other improper business practices in order to cause its customers to receive windfall profits from Medicare and Medicaid when submitting claims for certain drugs. The evidence further reveals that Bristol manipulated prices for the express purpose of expanding sales and increasing market share of certain drugs where the arranging of a financial benefit or inducement would influence the decisions of healthcare providers submitting the Medicare and Medicaid claims.

- 1. The BMS Group Controls the Published AWP for Its Products**

331. The BMS Group has controlled and set the AWPs for its pharmaceutical products through direct communications with industry compendia during the Class Period. In one BMS document, Denise Kaszuba, a senior BMS Group pricing analyst, instructed the *Red Book* that:

Effective immediately, Bristol-Myers Oncology Division products factor used in determining the AWP should be changed from 20.5% to 25%. This change should not effect [sic] any other business unit of Bristol-Myers Squibb Company.

332. Other internal documents clearly indicate that BMS had direct control over the spread between its states wholesale price and the published AWP. A BMS office dispatch dated September 9, 1992 notes the need for a mark up of the AWP over the state wholesale price. "After reviewing the results of the wholesaler survey performed by Bristol Oncology . . we have determined that for those items with a labeler 0003, we will use a 1.25 mark-up and for those

items with the labeler 00015, we will use a 1.20 mark-up. We noticed too, that FDB and Redbook use a 1.20 for everything.” (BMSAWP/0011246).

2. BMS's AWP Manipulation Benefited Providers at the Expense of the Class

333. BMS was well aware that providers and other purchasers of its drugs were using the spread to determine whether to purchase its drugs. Indeed, BMS was aware of and tracked the prices and AWPs of its competitors in order to remain competitive. In an internal BMS memorandum, BMS identifies its competitors who sell etoposide (Gensia, Pharmacia, Abbott, Chiron, Ben Venue, Immunex and Astra) and their corresponding list price and AWPs. (BMS3CA/000128).

334. BMS created AWP competitor analyses that tracked the AWPs of its competitors' relevant drugs, and used that date internally to propose suggested AWPs for BMS drugs. One such competitor analysis set forth the competitor AWPs for Atenolol with chlorthalidone and provided an “Apothecon suggested AWP” for each dosage. (BMS3CA/000648)

335. BMS clearly believed that the maintenance of a spread on its drugs was important in gaining and maintaining market share. In an internal BMS document, concerning its drug Vepacid (etoposide), BMS noted:

The Etopophos product file is significantly superior to that of etoposide injection Currently, physician practice can take advantage of the growing disparity between Vepesid's list price (and, subsequently, the Average Wholesale Price) and the actual acquisition cost when obtaining reimbursement for etoposide purchases. If the acquisition price of Etopophos is close to the list price, the physician's financial incentive for selecting the brand is largely diminished.

3. Specific BMS AWPs Documented by the DOJ

336. In a report published by the DHHS, the DOJ documented numerous instances where the published AWPs for various dosages of five (5) drugs manufactured by the BMS Group were substantially higher than the actual prices listed by wholesalers. The chart below sets forth the BMS Group drugs identified by the DOJ and the spread associated with one

particular dosage of each drug. These figures compare the DOJ's determination of an accurate AWP for that particular dosage, based upon wholesalers' price lists, with the AWP reported by the BMS Group in the 2001 *Red Book*.

Drug	Manufacturer	BMS's 2001 Red Book AWP	DOJ Determined Actual AWP	Difference	Percentage Spread
Amikacin Sulfate	Apothecon	\$32.89	\$17.31	\$15.58	90%
Amphotericin B	Apothecon	\$17.84	\$6.20	\$11.64	188%
Bleomycin Sulfate	BMS	\$609.20	\$509.29	\$99.91	20%
Cyclophosphamide	BMS	\$102.89	\$45.83	\$57.06	125%
Etoposide (Vepesid)	BMS	\$136.49	\$34.30	\$102.19	298%

337. Other sources reveal additional evidence of fraudulent AWPs for drugs manufactured and marketed by the BMS Group:

4. Other AWPs Related to VEPESID (etoposide)

338. The February 27, 2001 letter from Rep. Stark to BMS noted that as to BMS "... the manipulated discrepancies between [BMS's] inflated AWPs and DPs versus their true costs are staggering. For example, in the 2000 edition of the *Red Book*, Bristol reported an AWP of \$1296.64 for . . . Vepesid (Etoposide) for injection . . . while Bristol was actually offering to sell the exact same drug to [a large national group purchasing organization] for \$70.00." The difference noted by Rep. Stark represents a % 1,752 spread related to Vepecid.

5. Other AWPs Related to Blenoxane

339. BMS internal documents reveal that in 1995, BMS set the *Red Book* AWP for Blenoxane at \$276.29. At the same time, BMS was selling Blenoxane to oncologists practicing in St. Petersburg, Florida for only \$224.22. In 1996, BMS increased its reported AWP for Blenoxane to \$291.49, while continuing to sell the drug to oncologist for \$224.27. In 1997, BMS falsely reported that it had increased the AWP of Blenoxane to \$304.60, when in reality, BMS had lowered the price to oncologists to \$155.00. In 1998, BMS again reported a false AWP for Blenoxane of \$304.60 while further reducing the actual price to oncologists to \$140.00.

6. The BMS Group Provided Free Goods and Other Incentives

340. As part of its scheme the BMS Group also used free drugs and other goods to encourage participation by physicians. Thus, for example, the BMS Group provided free Etopophos® to two Miami oncologists in exchange for their agreement to purchase other BMS Group cancer drugs. Similarly, other documents show that the BMS Group provided free Cytogards in order to create a lower-than-invoice cost to physicians that purchased other cancer drugs through OTN. (A Cytogard is a device that prevents spillage of intravenous administered treatments such as BMS's cancer drug Etopophos®.)

341. As set forth above, the BMS Group's scheme to inflate its reported AWPs, market the resulting spread, and channel to providers "free" goods – all in order to increase the market share of its drugs – has resulted in excessive overpayments by Plaintiffs and the Class.

342. For example, in a report published by DHHS, the DOJ documented at least 12 instances where the published AWPs for drugs manufactured by the BMS Group were substantially higher than the actual prices listed by wholesalers.

343. The chart below sets forth five examples where the BMS Group deliberately inflated AWPs that it reported for BMS Group drugs. These figures compare the DOJ's determination of an accurate AWP, based upon wholesalers' price lists, with the AWP reported by the BMS Group in the 2001 *Red Book*.

Drug	Manufacturer	BMS's 2001 Red Book AWP	DOJ Determined Actual AWP	Difference	Percentage Spread
Amikacin Sulfate	Apothecon	\$32.89	\$17.31	\$15.58	90%
Amphotericin B	Apothecon	\$17.84	\$6.20	\$11.64	188%
Bleomycin Sulfate	BMS	\$609.20	\$509.29	\$99.91	20%
Cyclophosphamide	BMS	\$102.89	\$45.83	\$57.06	125%
Etoposide (Vepesid)	BMS	\$136.49	\$34.30	\$102.19	298%

344. In 1997, an OIG Report identified three other Medicare Part B drugs with inflated AWPs – which the 1997 *Red Book* indicates were manufactured only by the BMS Group at that

time: Paraplatin® (carboplatin), Rubet® (doxorubicin hydrochloride), and Taxol® (paclitaxel). Sales of these inflated drugs were substantial. For example, Paclitaxel generated \$941 million in revenue for the BMS Group in 1997, and Carboplatin generated \$702 million in revenue in 2001.

345. The government's investigation uncovered other drugs for which the BMS Group was stating a fraudulent AWP. Specifically:

- a. In the 2000 edition of the *Red Book*, BMS reported an AWP of \$1296.64 for Vepesid (Etoposide) for injection while BMS was actually offering to sell the exact same drug to a large customer for only \$70.00.
- b. From 1995 through 1998 the *Red Book* listed AWP for BMS' Blenoxane 15u increased from \$276.29 to \$304.60, while the actual cost to physicians declined from \$224.22 to \$140.00, resulting in a spread of \$164.60 in 1998

346. An internal BMS Group document shows that the AWP set by the BMS Group for its drugs bears no relation to an *actual* wholesale price, and is greater than the highest price actually paid by providers. More specifically, in a discussion about lowering Vepesid's AWP in order to create sales for Etopophos, the BMS Group stated that the "AWP for Vepesid would be reduced from its current level to the highest bid price currently in the marketplace."

347. BMS Group documents also reveal that physicians were making medical decisions based on how much profit they could make from the AWP manipulated spread. In considering provider choice between BMS drugs Etopophos® and Vepesid® (Etoposide), the BMS Group noted that:

The Etopophos product file is significantly superior to that of etoposide injection Currently, physician practice can take advantage of the growing disparity between Vepesid's list price (and, subsequently, the Average Wholesale Price) and the actual acquisition cost when obtaining reimbursement for etoposide purchases. If the acquisition price of Etopophos is close to the list price, the physician's financial incentive for selecting the brand is largely diminished.

348. While the BMS Group and other Defendants have placed the blame for setting published AWPs on the publications in which the AWPs are contained, another BMS Group

document demonstrates that publications reporting AWPs had no discretion to set AWPs, and instead published verbatim the prices reported by the BMS Group and other Defendants. In the document, Denise Kaszuba, a senior BMS Group pricing analyst, instructed the *Red Book* that:

Effective immediately, Bristol-Myers Oncology Division products factor used in determining the AWP should be changed from 20.5% to 25%. This change should not effect [sic] any other business unit of Bristol-Myers Squibb Company.

J. Dey

349. Dey engages in an organization-wide and deliberate scheme to inflate AWPs.

Dey has stated fraudulent AWPs for all or almost all of its drugs, including those set forth below. The specific drugs of Dey for which relief is sought in this case are set forth in Appendix A, and are identified below:

Manufacturer	Brand Name (if applicable)	Generic Name	Therapeutic Category/Usage
DEY		acetylcysteine	Mucolytic (Respiratory Agent: Diagnostic Aid) Used for certain lung conditions when increased amounts of mucus make breathing difficult
		albuterol or albuterol sulfate	Bronchodilator (Respiratory Agent) Used for relief of bronchospasm in asthma sufferers
		cromolyn sodium	Antiallergic and Mast Cell Stabilizer Used to help prevent or treat the symptoms of seasonal or chronic allergic rhinitis
		ipratropium bromide	Bronchodilator (Respiratory Agent) Used for relief of bronchospasm in asthma sufferers
		metaproterenol sulfate	Bronchodilator (Respiratory Agent) Used for relief of bronchospasm in asthma sufferers

1. Dey Has Been the Target of Government Investigations

350. In connection with its scheme to inflate AWPs, Dey has been investigated by the United States Department of Justice, United States Department of Health and Human Services, Office of Inspector General, the United States District Attorney for the District of Massachusetts,

the Attorney General of the State of California, the Attorney General for the State of Texas, the Attorney General of the State of Connecticut, and the District Attorney for the County of Suffolk, New York State.

351. These investigations confirm that Dey has engaged in a deliberate scheme to inflate the published AWPs for many of its drugs. For instance, Dey's spread for albuterol sulfate, a drug that constituted 37 % of Dey's income in 1998, drastically increased between 1992 and 1998. In 1992, Dey's *Red Book* AWP for albuterol sulfate (.083% concentration, 3 ml) was \$32.30. McKesson's wholesale price for the drug was \$25.45 (a spread of \$ 6.85 or 27%). By 1998, Dey's *Red Book* AWP for the same concentration/dose of albuterol sulfate had barely slipped to \$30.25, while McKesson's wholesale price had plummeted to \$10.00 (a spread of \$20.25 or 202%). See September 25, 2000 letter from U.S. Rep. Bliley to Nancy-Ann Min DeParle.

352. The federal government is not the only entity to uncover Dey's scheme to inflate AWPs. The Attorneys General of Texas and West Virginia recently discovered that due to over inflated AWPs, both state's Medicaid Programs have been defrauded by Dey for millions of dollars. Texas alleges that, between 1995 and 1999, it paid \$13.7 million for Dey's albuterol sulfate and ipratropium bromide, when it should have paid only \$8.7 million – an overcharge of \$5 million. West Virginia alleges that Dey and others manipulated the AWP to significantly overcharge state agencies and residents for several drugs, including albuterol, from at least 1995 through 2000.

353. In its own suit against Dey and other pharmaceutical manufacturers for AWP manipulation, the Attorney General for the State of Connecticut documented significant spreads between Dey's published AWPs and actual wholesale prices for many of its drugs. Incorporated below are examples cited by the Connecticut Attorney General:

Drug	NDC #	Year	AWP	ACTUAL PRICE	SPREAD	% OVERCHARGE
ALBUTEROL	49502-0303-17	1996	\$21.70	\$3.25	\$18.45	488%
IPATROPIUM BORMIDE	49502-0685-03	2001	\$44.10	\$8.35	\$35.58	355%
IPATROPIUM BROMIDE	49502-0685-03	2000	\$44.10	\$11.45	\$32.65	239%
IPATROPIUM BROMIDE	49502-0685-03	1999	\$44.10	\$11.45	\$30.11	177%

1. Dey Controls the Published AWP for Its Products

354. Dey has controlled and set the AWPs for its pharmaceutical products through direct communications with industry compendia during the Class Period. Dey's own documents indicate that it initially set both the AWP and WAC for its products and also regularly approved subsequent AWPs and WACs published by industry compendia. For example:

a. In a January 13, 1996 letter from Dey to First Data Bank, Day announced the availability of a new ipratropium bromide inhalation solution. The letter includes the following instructions to First Data Bank:

“Effective immediately, please update your database to reflect the introduction of this new DEY product as follows:

NDC/ Order Number	Description	Vial Size	Strength	Units per Ctn	Ctns per Case	AWP	WAC
49502-685-03	Ipatropium Bromide Inhalation Solution 2.0%	2.5ml	0.5mg/2.5ml	25	12	\$44.10	\$25.50
49502-685-60	Ipatropium Bromide Inhalation Solution 2.0%	2.5ml	0.5mg/2.5ml	60	12	\$105.60	\$60.90

(DL-CA00120) (Confidential)

b. In a 1998 worksheet produced by *Red Book* to Dey in order to verify its listings of Dey products, an employee of Dey went through each of the Dey products listed in the *Red Book* and approved each of the AWPs and WACs for each of its products. Handwritten

comments on the document include the notation “9/11/98 – checked AWP & WAC pricing (backup attached)” (DL-CA 00080) (Confidential).

2. Dey's AWP Manipulation Benefited Providers at the Expense of the Class

355. The purpose of Dey's AWP manipulation was to increase the spread in order to maximize the profit to providers and other intermediaries. This is clear from Dey's own documents. For example:

a. Dey was aware that its customers were “spread shopping” and competed by increasing the spread to its customers. In an internal worksheet filled out by Dey in preparation for a bid of potential sales to one of its customers, Dey listed the current contract price of various products as well as a recommended new contract price. In the notes next to these figures the worksheet states, “This account needs AWP-40% or better to see profit due to the employer groups they serve. Have not made the switch to our product line due to the spread . . .” (DL-TX-0014029)

b. Competition between generic products produced by Dey was fierce and the spread was a major factor in this competition. In another similar bid price worksheet for a different customer, the corresponding notes state “cromolyn pricing is at AWP-40% and 35% respectively – bear in mind that we are competing with the branded spread and the generic perception of [sic] everything should be AWP-60%” (DL-TX-0014439)

356. This competition came at the expense of Plaintiffs and the Class whose payments were based on AWP. For instance, Albuterol sulfate, a multisource drug and one of Dey's top selling products, was a focus of the federal government's investigation into AWP inflation. OIG found that “Medicare's reimbursement amount for albuterol was nearly six times higher than the median catalog price” and that “Medicare and its beneficiaries would save between \$226 million and \$245 million a year if albuterol were reimbursed at prices available to suppliers.” See “Excessive Medicare Reimbursement for Albuterol,” OEI-03-01-00410, March 2002.

357. The OIG determined that the Medicare-allowed amount for albuterol sulfate in 1996 was \$0.42. However the actual wholesale price was \$0.15, and the highest available wholesale price was \$0.21.

358. GAO also found that albuterol sulfate was one of a small number of products that accounted for a large portion of Medicare spending and volume. More specifically, albuterol sulfate ranked first in volume of units covered by Medicare, accounting for 65.8% of total units reimbursed. Furthermore, albuterol sulfate accounted for 6.3% of total Medicare spending, ranking fifth out of more than 400 covered drugs. *See* GAO Report to Congressional Committees, MEDICARE: Payments for Covered Outpatient Drugs Exceed Providers' Cost, Tables 1 and 2, pp. 7-8.

3. Specific Dey AWPs Documented by the DOJ

359. In a report published by the DHHS, the DOJ documented at least 15 instances where the published AWPs for various dosages of 4 drugs manufactured by Dey were substantially higher than the actual prices listed by wholesalers. The chart below sets forth the drugs identified by the DOJ and the spread associated with one particular dosage of each of the 4 drugs. These figures compare the DOJ's determination of an accurate AWP for that particular dosage, based upon wholesalers' price lists, with the AWP reported by Dey in the 2001 *Red Book*.

Drug in Lowest Dosage Form	2001 Red Book AWP	DOJ Determined AWP	Difference	Percentage Spread
Acetylcysteine	\$59.88	\$25.80	\$34.08	132%
Albuterol Sulfate	\$30.25	\$9.17	\$21.08	230%
Cromolyn Sodium	\$42.00	\$23.01	\$18.99	82%
Metaproterenol Sulfate	\$30.75	\$11.29	\$19.46	172%

4. Inflated Dey AWPs From Dey's Price Lists

360. According to Dey's own documents, the published AWPs for many of its own products were higher than the actual prices charged wholesalers and other intermediaries.

Table 1 below is excerpted from a pricing proposal by Dey to McKesson Drug Company, one of the county's largest wholesalers, dated December 20, 1995.

Table 1

Generic Name	Strength	Size	AWP	WAC	Suggested Sell Price	% Discount from WAC	% Spread
Acetylcysteine Solution	10%	4 mL	\$67.80	\$25.80	\$18.00	-40.0%	277%
Acetylcysteine Solution	10%	10 mL	\$40.26	\$15.27	\$13.50	-30.0%	198%
Acetylcysteine Solution	10%	30 mL	\$110.48	\$41.97	\$33.50	-35.0%	230%
Acetylcysteine Solution	20%	4 mL	\$81.36	\$31.08	\$21.50	-40.0%	278%
Acetylcysteine Solution	20%	10 mL	\$48.66	\$18.57	\$16.20	-30.0%	200%
Acetylcysteine Solution	20%	30 mL	\$133.43	\$50.64	\$39.90	-35.0%	234%
Acetylcysteine Solution	20%	100 mL	\$92.21	\$75.90	\$59.90	-40.0%	54%
Albuterol Sulfate Inhalation Soln.	0.083%	3 mL	\$30.25	\$14.50	\$12.00	-29.3%	152%
Albuterol Sulfate Inhalation Soln.	0.083%	3 mL	\$36.30	\$17.40	\$14.40	-29.3%	152%
Albuterol Sulfate Inhalation Soln.	0.083%	3 mL	\$72.60	\$34.50	\$28.80	-28.7%	152%
Cromolyn Sodium Inhalation, USP	20 mg/2ml	2 mL	\$42.00	\$34.20	\$29.00	-25.0%	45%
Cromolyn Sodium Inhalation, USP	20 mg/2ml	2 mL	\$84.00	\$66.00	\$58.00	-22.3%	45%
Metaproterenol Sulfate Inhalation Soln.	0.4%	2.5 mL	\$30.75	\$11.00	\$10.00	-21.5%	207%
Metaproterenol Sulfate Inhalation Soln.	0.6%	2.5 mL	\$30.75	\$11.00	\$10.00	-21.5%	207%
Sodium Chloride Solution	0.9%	3 mL	\$24.20	\$13.00	\$10.94	-32.7%	121%
Sodium Chloride Solution	0.9%	5mL	\$24.20	\$13.00	\$10.94	-32.7%	121%

(DL-TX 0011179)

5. Dey Provided Free Goods and Other Incentives

361. In addition to marketing the spread, Dey has utilized other impermissible inducements to stimulate sales of its drugs without accounting for them in its WAC or AWP. These inducements were designed to result in a lower net cost to the provider while concealing the actual wholesale price beneath a high invoice price. By utilizing "off-invoice" inducements, Dey provided purchasers with substantial discounts meant to gain their patronage while maintaining the fiction of a higher wholesale price.

362. For example, in an announcement of a special incentive program to its customers to induce the purchase of its Ipratropium Bromide Inhalation solution, Dey sent its customers an offer sheet entitled “Profitability Enhancement For You” in which it stated “For every dollar of Dey Cromolyn Sodium unit-dose purchased, Dey will provide free goods of either: Coromolyn Sodium Inhalation Solution 0.02%, 2.5ml, at 1.0 times the rebate amount -OR- Ipatropium Bromide Inhalation Solution 0.02%, 2.5ml, when it launches, at a value of 1.5 times the rebate amount for Cromolyn.” (DL-TX-0004775).

6. Dey Has Concealed Its AWP Manipulation

15. In an effort to conceal the existence of a spread from end payors, Dey concealed the true wholesale prices of its drugs. For instance, in a handwritten memorandum to Dey’s pricing committee a potential pricing structure with a customer was discussed:

“I met with IPC to discuss our contract offer (illegible). . . Tom Konnelly (IPC) said he wanted to keep net pricing hidden from 3rd parties by increasing in the purchase price on our offer by 25%. IPC then requires a 25% rebate back to IPC. . . I have remarked the pricing. If this offer is accepted, the higher price will go into McKesson as a chargeback contract. Dey will then rebate IPC 25% on contract purchases on a quarterly basis. . .”

(DL-TX-0024844)

363. As set forth above, Dey’s scheme to inflate its reported AWPs and market the resulting spread to increase the market share of its drugs and its use of other “off invoice” rebates and financial inducements to its customers has resulted in excessive overpayments by Plaintiffs and the Class.

K. The Fujisawa Group (Fujisawa Pharmaceutical, Fujisawa Healthcare, Fujisawa USA)

364. Fujisawa engages in an organization-wide and deliberate scheme to inflate AWPs. Fujisawa has stated fraudulent AWPs for all or almost all of its drugs, including those set forth below. The specific drugs of Fujisawa for which relief is sought in this case are set forth in Appendix A and are identified as follows:

Manufacturer	Brand Name (if applicable)	Generic Name	Therapeutic Category/Usage
FUJISAWA GROUP (Fujisawa Healthcare, Fujisawa Pharmaceutical and Fujisawa USA)	Aristocort	triamcinolone, triamcinolone diacetate or triamcinolone acetonide	Anti-Inflammatory, Steroidal; Used in the treatment of asthma
	Aristospan	triamcinolone hexacetonide	Anti-Inflammatory Agent, Steroidal Used to provide relief for inflamed areas of the body
	Cefizox	ceftizoxime sodium or ceftizoxime in d5w	Antibiotic Agent (Anti-Infective Agent) General antibiotic
	Cyclocort	amcinonide	Anti-Inflammatory Agent Used to treat inflammatory symptoms of skin disorders
	Lyphocin	vancomycin hydrochloride	Antibacterial Agent Used to treat infections in many different parts of the body
	Nebupent	pentamidine isothionate	Antiprotozoal Agent Used to try to prevent Pneumocystis carinii pneumonia
	Pentam 300	pentamidine isethionate	Anti-Infective Agent Used in the treatment of pneumonia
	Prograf	tacrolimus	Immunosuppressant Used to lower the body's natural immunity in patients who receive organ transplants
		acyclovir sodium	Antiviral Agent Used to treat herpes simplex infections, varicella-zoster (chickenpox) in people with weakened immune systems, and severe genital herpes infections
		dexamethasone sodium phosphate	Anti-Inflammatory Agent; Antiemetic (Gastrointestinal Agent) Used in various applications to treat inflamed areas of the body
		doxorubicin hydrochloride	Antineoplastic Used in the treatment of ovarian cancer and AIDS-related Kaposi's sarcoma
		fluorouracil	Antineoplastic Used to treat cancer, including colon, rectum, breast, stomach, and pancreas
		gentamicin sulfate	Antibacterial Agent Used to treat serious bacterial infections
		vinblastine sulfate	Antineoplastic Used in the treatment of various forms of cancer, including lymphoma and breast cancer

1. Fujisawa Has Been the Target of Government Investigations

365. In connection with its scheme to inflate AWPs, Fujisawa has been investigated by the United States Department of Justice, the Office of Inspector General of the Department of Health and Human Services, the Attorney General for the State of Texas, and the Attorney General for the State of California.

1. Fujisawa Controls the Published AWP for Its Products

366. Fujisawa controlled and set the AWPs for its pharmaceutical products through direct communications with industry compendia during the Class Period. For example, on March 10, 1997, Fujisawa provided MediSpan with an updated listing of pack prices – including AWPs – for all of its products. (FJ-MDL 015152-015159).

2. Fujisawa's AWP Manipulation Benefited Providers at the Expense of the Class

367. The purpose of Fujisawa's manipulation was to increase the spread in order to maximize the profit to providers and other intermediaries at the expense of Plaintiffs and the Class. Fujisawa understood that providers and intermediaries sought significant AWP spreads. In a March 1995 Monthly Report, dated March 30, 1995, Fujisawa noted:

We have lost our Vanco business at Chartwell. They have recently been handed an edict to order those products with the largest spread between acquisition cost and AWP. Abbott has unbelievably high Vanco AWP. In an effort to counter this loss I suggested we look at picking up the Cefazolin business where our AWP for one gram Cefazolin is over \$8. Unfortunately our 10 gram price does not follow the same formula and is in the \$45 range while Schein is approximately \$58. We do however have a shot at Cefizox for Medicaid/Medicare patients which make up 50% of Chartwell's patients. Medicaid does not reimburse Chartwell for the Rocephin they currently use and while they will not reimburse for Cefizox either they could acquire Cefizox at a fraction of the cost. They use \$400,000 in Rocephin annually, \$200,000 for Medicaid/Medicare patients. That works out to better than \$100K in savings for Chartwell.

(FJ-MDL 005687-88) (Confidential).

368. Fujisawa, in a conscious effort to increase the spread for providers and intermediaries, changed its AWPs and marketing practices accordingly. In a May 1995 Monthly Report, dated May 30, 1995, Fujisawa addressed its recent decision to increase its AWP for Vancomycin Hydrochloride and aggressively market the resulting spread increase:

Many thanks to Rick and Bruce for adjusting the AWP on the five gram Vanco. This should lead to more business. As I have previously reported, some companies are still using AWP for reimbursement purposes. Chartwell has been told to search for the largest spread and order accordingly. I would have liked to see us match Abbott's AWP for our complete Vanco, and Cefazolin line. I will settle for the five gram at \$1 below Abbott but that means that we still have to compete at the other end of the equation. For example, if Abbott's AWP is \$163 and their contract is \$30 and if our AWP is \$162 we will have to be at least \$29 to have the same spread. Follow?

(FY-MDL 005668-69) (Confidential).

369. In an October 5, 1993 interoffice memorandum discussing Fujisawa's communications with industry pricing compendia, Fujisawa acknowledged that the AWPs for nearly all of its products is inflated at least 33% over direct list prices:

One of the issues regarding our companies AWP listing is that the databases only use our listing as a "Suggested Manufacturers AWP". The standard wholesaler mark-up used by those databases is currently at 25% above direct list price which is our hospital list. Almost all of our products are at 33% or higher above list price.

(FJ-MDL 008346) (Confidential).

370. Further, just as Fujisawa motivates providers to administer drugs based on the AWP, Fujisawa rewards PBMs based on the degree of influence they exert to drive utilization of Fujisawa products. (FJ-MDL 010272-78) (Confidential).

3. Specific Fujisawa AWPs Documented by the DOJ

371. In a report published by the DHHS (AB-00-86), the DOJ documented at least 35 instances where the published AWPs for various dosages of 6 drugs manufactured by Fujisawa were substantially higher than the actual prices listed by wholesalers. The chart below sets forth

the 6 drugs identified by the DOJ and the spread associated with one particular dosage of each drug. These figures compare the DOJ's determination of an accurate AWP for that particular dosage, based upon wholesalers' price lists, with the AWP reported by Fujisawa in the 2001 *Red Book*.

Drug	The Fujisawa Group's 2001 Red Book AWP	DOJ Determined Actual AWP	Difference	Percentage Spread
Acyclovir Sodium	\$565.10 ³	\$371.50	\$193.60	52%
Dexamethasone Sodium Phosphate	\$1.04 ⁴	\$.66	\$.38	58%
Fluorouracil	\$2.87	\$1.20	\$1.67	139%
Gentamacin Sulfate	\$12.64 ⁵	\$5.40	\$7.24	134%
Pentamidine Isethionate	\$98.75	\$36.00	\$62.75	174%
Vancomycin Hydrochloride	\$10.97 ⁶	\$7.00	\$3.97	57%

(P006299-006316).

4. Inflated AWPs From Fujisawa Price Lists

372. In response to government subpoenas, Fujisawa produced numerous price lists setting forth spreads between AWPs and prices offered to wholesalers, providers and other intermediaries. A review of those price lists reveals that Fujisawa has consistently offered drugs and other solutions to its customers at prices significantly below the published AWP and that the spread was of great importance to its customers. To repeat every one of those drugs and the spreads offered to each specific customer here is not practical.

373. Set forth below in Table 1, however, are the AWP, contract prices and spread of a number of drugs (not already referenced above) included in a Fujisawa customer price list dated August 24, 1995, and their associated AWP spread. (FJ-MDL 013079-81) (Confidential).

³ Calculation based on the AWP listed in the 1998 *Red Book*.

⁴ Calculation based on the AWP listed in the 1998 *Red Book*.

⁵ Calculation based on the AWP listed in the 1998 *Red Book*.

⁶ Calculation based on the AWP listed in the 1998 *Red Book*.

Table 1

Drug	Contract Price	AWP	\$ Diff AWP	% Spread
Triamcinolone	\$14.33	\$17.95	\$3.62	25%
Calcium Gluconate	\$11.50	\$34.00	\$22.50	196%
Cefazolin Sodium	\$139.00	\$367.13	\$228.13	164%
Ceftizoxime Sodium	\$7.50	\$11.86	\$4.36	58%
Amcinonide	\$41.50	\$52.13	\$10.63	26%
Doxycycline Hyclate	\$15.00	\$73.75	\$58.75	392%
Fluphenazine Hydrochloride	\$24.10	\$30.25	\$6.15	25%
Folic Acid	\$7.25	\$11.85	\$4.26	63%
Levothyroxine Sodium	\$3.90	\$38.43	\$34.53	885%
Lidocaine Hydrochloride	\$17.00	\$24.50	\$7.50	44%
Magnesium Sulfate	\$22.00	\$138.25	\$116.25	528%
Mannitol	\$28.00	\$56.50	\$28.50	101%
Neostigmine Methylsulfate	\$8.20	\$89.30	\$81.10	989%
Oxytocin	\$13.50	\$24.50	\$11.00	81%
Potassium Acetate	\$92.00	\$312.40	\$220.40	240%
Potassium Chloride	\$12.25	\$30.50	\$18.25	149%
Potassium Phosphate	\$30.25	\$133.75	\$103.50	342%
Pyridoxine Hydrochloride	\$35.00	\$47.00	\$12.00	34%
Scopolamine Hydrobromide	\$22.00	\$30.00	\$8.00	36%
Selenium	\$18.25	\$195.25	\$177.00	970%

374. Set forth below in Table 2, however, are the AWP, contract prices and spread of a number of drugs (not already referenced above) included in a Fujisawa price list dated November 5, 1996, and their associated AWP spread. (FJ-MDL 008240-53) (Confidential).

Table 2

Drug	Wholesaler Price	AWP	\$ Diff AWP	% Spread
Adenocard IV	\$21.95	\$26.34	\$4.39	20%
Adenoscan	\$179.00	\$223.75	\$44.75	25%
Aristocort A	\$7.05	\$8.46	\$1.41	20%
Atropine Sulfate Injection	\$.64	\$1.12	\$.48	75%
Doxorubicin	\$12.44	\$45.50	\$33.06	266%
Furosemide	\$.74	\$.98	\$.24	32%

Drug	Wholesaler Price	AWP	\$ Diff AWP	% Spread
Hydroxyzine Hydrochloride	\$.42	\$.65	\$.23	55%
Protamine Sulfate	\$3.33	\$5.32	\$1.99	60%
Selepen	\$18.24	\$29.93	\$11.68	64%
Sodium Acetate	\$8.81	\$14.63	\$5.82	66%
Sodium Bicarbonate	\$2.04	\$3.33	\$1.29	63%
Sodium Chloride	\$.68	\$1.40	\$.72	106%
Sodium Phosphate	\$5.81	\$9.08	\$3.27	56%
Tracelyte	\$8.26	\$11.57	\$3.31	40%
Vinblastine Sulfate	\$26.50	\$43.23	\$16.73	63%
Water for Injection	\$1.10	\$2.34	\$1.24	113%

375. As set forth above, Fujisawa's scheme to inflate its reported AWPs and market the resulting spread to increase the market share of its drugs has resulted in excessive overpayments by Plaintiffs and the Class.

L. The GSK Group (GlaxoSmithKline, SmithKline Beecham, Glaxo Wellcome)

376. The GSK Group has engaged in an organization-wide and deliberate scheme to inflate AWPs. The GSK Group has stated fraudulent AWPs for all or almost all of its drugs, including those set forth below. The specific drugs manufactured and/or distributed by the GSK Group for which relief is sought in this case are set forth in Appendix A and are identified below:

Manufacturer	Brand Name (if applicable)	Generic Name	Therapeutic Category/Usage
GSK GROUP (SmithKline	Advair Diskus	salmeterol-fluticasone	Bronchodilator (Respiratory Agent) Used for treatment of asthma
Beecham, GlaxoSmithKline and Glaxo Wellcome)	Agenerase	amprenavir	Antiviral Agent Used in treatment of HIV infection
	Alkeran	melphalan	Antineoplastic Used to treat ovarian cancer and a certain type of cancer in the bone marrow
	Amerge	naratriptan succinate	Antimigraine Agent Used for treatment of migraine attacks
	Beconase AQ	beclomethasone dipropionate monohydrate	Anti-Inflammatory Agent Used to treat discomfort of hay fever, other allergies, and other nasal problems

Manufacturer	Brand Name (if applicable)	Generic Name	Therapeutic Category/Usage
	Ceftin	cefuroxime axetil	Antibacterial Agent Used to treat infections caused by bacteria
	Combivir	lamivudine-zidovudine	Antiviral Agent Used in treatment of HIV infection
	Daraprim	pyrimethamine	Antiprotozoal Used for treatment of malaria and other protazoal infections
	Epivir	lamivudine	Antiviral Agent Used in treatment of HIV infection
	Flonase	fluticasone propionate (nasal)	Anti-Inflammatory Agent Used for treatment of allergic and nonallergic rhinitis
	Flovent	fluticasone propionate (inh)	Antiasthmatic (Anti-Inflammatory Agent) Used for treatment of asthma
	Imitrex	sumatriptan or sumatriptan succinate	Antimigraine Agent Used for treatment of migraine attacks or cluster headaches
	Kytril	granisetron hcl	Antiemetic (Gastrointestinal Agent) Used to prevent the nausea and vomiting that may occur after chemotherapy
	Lamictal	lamotrigine	Anticonvulsant Used to help control some types of seizures in the treatment of epilepsy
	Lanoxin	digoxin	Antiarrhythmic Agent (Cardiovascular Agent) Used to improve the strength and efficiency of the heart, or to control the rate and rhythm of the heartbeat.
	Leukeran	chlorambucil	Alkylating Agent (Antineoplastic) Used to treat cancer of the blood and lymph system
	Mepron	atovaquone	Antiprotozoal Used to treat and to prevent pneumonia
	Myleran	busulfan	Antineoplastic Used to treat some kinds of cancer of the blood.
	Navelbine	vinorelbine tartrate	Antineoplastic Used for treatment of lung cancer
	Paxil	paroxetine hcl	Antianxiety agent; Antidepressant (Psychotherapeutic Agent) Used in the treatment of various psychotherapeutic disorders
	Purinethol	mercaptopurine	Antimetabolite (Antineoplastic) Used to treat some kinds of cancer.

Manufacturer	Brand Name (if applicable)	Generic Name	Therapeutic Category/Usage
	Relenza	zanamivir	Antiviral Agent Used in the treatment of the infection caused by the flu virus (influenza A and influenza B).
	Retrovir	zidovudine	Antiviral Agent Used for treatment of HIV infection
	Serevent	salmeterol xinafoate	Bronchodilator (Respiratory Agent) Used to treat or prevent symptoms of asthma, chronic bronchitis, emphysema, and other lung diseases
	Trizivir	abacavir sulfate-lamivudine-zidovudine	Antiviral Agent Used for treatment of HIV-1 infection
	Valtrex	valacyclovir hcl	Antiviral Agent Used for treatment of shingles and genital herpes
	Ventolin HFA	albuterol sulfate	Bronchodilator (Respiratory Agent) Used for treatment or prevention of bronchospasm
	Wellbutrin	bupropion hcl	Antidepressant (Psychotherapeutic Agent) Used for treatment of depression
	Zantac	rantidine hydrochloride	Gastrointestinal Agent Used in the treatment of active duodenal ulcer
	Ziagen	abacavir sulfate	Anti Infective Agent Used in the treatment of HIV infection
	Zofran	ondansetron hcl	Antiemetic (Gastrointestinal Agent) Used to treat or prevent the nausea and vomiting that may occur after chemotherapy
	Zofran ODT	ondansetron	Antiemetic (Gastrointestinal Agent) Used to treat or prevent the nausea and vomiting that may occur after chemotherapy
	Zovirax	acyclovir	Antiviral Agent Used for treatment of shingles, genital herpes and herpes simplex
	Zyban	bupropion hcl	Antidepressant (Psychotherapeutic Agent) Used to relieve mental depression. Also used to aid in cessation of smoking
		thioguanine	Antineoplastic Used to treat some kinds of cancer

1. The GSK Group Has Been the Target of Government Investigations

377. In connection with its scheme to inflate AWPs, the GSK Group has been investigated by the United States Department of Justice, the Office of Inspector General of the

Department of Health and Human Services, the Attorney General for the State of Texas, the Attorney General for the State of California, and the Attorney General for the State of Nevada, Medicaid Fraud Control Unit.

378. These investigations confirm that the GSK Group has engaged in a deliberate scheme to inflate the published AWPs for its drugs.

1. The GSK Group's Definition and Understanding of AWP

379. In a GSK document entitled "Zofran Tablets & Zofran Injection: Sales Training Guide Reimbursement Module" (GSK-MDL-ZN02-035925) (Highly Confidential), GSK defines AWP as follows:

Average Wholesale Price (AWP): The composite wholesale prices charged on a specific commodity that is assigned by the drug manufacturer and is listed in either the Red Book or Blue Book and used by third-party payers as a basis for reimbursement.

(GSK-MDL-ZN02-035985) (Highly Confidential). Thus, by its own definition, GSK recognizes that: (i) AWP should be an average of actual wholesale prices; (ii) the drug manufacturers control the published AWP; and (iii) the published AWPs directly affect the payments made by the Class.

2. The GSK Group Controls the Published AWP for Its Products

380. The GSK Group has controlled and set the AWPs for its pharmaceutical products during the Class Period. As set forth below, any claim that The GSK Group only reports a WAC to industry compendia and therefore is not responsible for the published AWPs is belied by its own documents. For example:

a. In 1991 a Glaxo document entitled "Zofran Third Party Payment Plan," among the many recommendations concerning the pricing of its then new drug Zofran was the recommendation that "In establishing direct-to-wholesaler and *Red Book* wholesale prices for Zofran, Glaxo should take into consideration physicians' expected profit margins." (GSK-MDL-ZN02-03428) (Highly Confidential).

b. Expanding further on the recommendation above, elsewhere in the same document it is stated: “Because insurers often reimburse physician-infused drugs up to the average wholesale price (AWP), the doctor’s profits are determined by the differential between the AWP and the price they pay to the wholesaler or pharmacy supplier. The company should ensure that doctors will make acceptable return on Zofran® by managing markups through the distribution chain.” (GSK-MDL-ZN02-034366) (Highly Confidential).

381. As do all of the Defendants, GSK has direct control over the “markups” in the distribution chain for its products. That control results from an ability to set the published AWP.

3. The GSK Group’s AWP Manipulation Benefited Providers at the Expense of Plaintiffs and the Class

382. GSK acknowledged that the AWP, as published in industry compendia, was used as the basis for most payments by third party payors. GSK’s own documents state, “Most, but not all, plans determine a payment for new drugs, based on the drug’s cost as listed in the *Red Book* and pay all providers that amount less any patient co-payments.” (GSK-MDL-ZN02-035965) (Highly Confidential). Elsewhere in the same document GSK acknowledges: “Payment amounts for most payers is usually based on the AWP as listed in *Red Book*, however, co-payments, especially for Zofran Tablets will be required.” (GSK-MDL-ZN02-035973) (Highly Confidential).

383. The purpose of The GSK Group’s AWP manipulation was to increase the spread in order to maximize the profit to providers and other intermediaries at the expense of Plaintiffs and the Class. That scheme has resulted in a system where drugs are administered based upon a profit incentive to physicians and other intermediaries and which results in an incentive to prescribe more expensive, rather than cheaper drugs. In talking points prepared in advance of negotiations with clinics, Glaxo instructed its sales people to remind customers that “Cheaper is not necessarily a prudent medical or business decision” and that “Cheaper ≠ Good medicine or Good Business!” (GSK-MDL-ZN02-077818-19) (Highly Confidential).

384. The GSK Group tried to maximize spread because it understood that its customers routinely engaged in “spread shopping” – comparing its AWPs with those of its competitors in order to determine the greatest spread (and therefore sell or administer the drug with the greatest spread).

385. Perhaps the most flagrant example of the GSK Group’s fraudulent manipulation of AWPs is found in the documents relating to Glaxo’s Zofran® and SKB’s Kytril®. These two drugs both minimize the nausea associated with chemotherapy, and, prior to the merger of Glaxo and SKB, competed head-to-head in the same market. As detailed below, much of that competition concerned which product could generate *the greater spread*, or profit, for physicians; not over which product was better for patients.

4. Glaxo’s Zofran®

386. A Glaxo marketing document, sent to its sales and marketing personnel via U.S. Mail and interstate wire facilities, advises that they should emphasize to medical providers both the benefits of Zofran® and the financial benefits of the spread. Specifically:

By using a 32 mg bag, the physician provides the most effective dose to the patient and increases his or her profit by \$_____ in reimbursement as well as paying no upcharges for the bag or admixing

387. A follow-up internal Glaxo memo, dated October 27, 1994, entitled “Zofran Pricing Recommendation,” states: “Physician reimbursement for the administration of intravenous oncology drugs is based on the spread between acquisition cost and the AWP.” The memo later notes that “Kytril carries a 20% spread between List Price and AWP compared to Zofran which carries a 16 2/3% spread providing SKB with a significant advantage in the clinic setting with respect to reimbursement.” (P007015-P007490, at P007487-P007490).

388. In response to the larger spread being offered on Kytril, this same internal document discusses several options to increase Zofran’s spread “to balance the reimbursement

spread which currently exists between Zofran and the market in which it competes. . . ." The pricing options considered for increasing the "spread" for Zofran® included:

Recommendation #1

4.5% price increase	\$178.97 to \$187.02
Increase AWP	16 2/3% to 20% \$214.76 to \$233.78 (8.5%)
3%Wholesaler Rebate (11/14/94 - 1/31/95)	\$187.02 to \$172.92 (chargeback) \$179.92 to \$167.31 (rebate)

389. In an effort to hide the fact that Glaxo was increasing the spread for Zofran®, Glaxo elected to not only increase its AWP and provide rebates, but to also include a small actual price increase. In describing the reason for an increase in the actual selling price, an internal Glaxo document states:

The recommended multi-tiered modification to current promotion, should also provide an immediate resultant impact to weekly unit sales without being easily intelligible by SKB as to the means by which this was achieved. Thus, providing additional time before a competitive response would be delivered.

390. Glaxo internal documents, however, recognized that as a result of its increasing the spread for Zofran®, SKB would have two options:

Option 1: Decrease the purchase price of Kytril.

Option 2: Take a price increase to raise the AWP while maintaining purchase price to generate a higher spread than \$52.00.

(P007015-P007490, at P007489-P007490).

391. In order to increase the spread for Zofran®, Glaxo increased the AWP for a 20 ml injection of Zofran® to \$233.02 in January of 1995. This was discussed in an October 27, 1994 memo entitled "Zofran Pricing Recommendation" and further discussed at a Glaxo pricing committee meeting on November 4, 1994. (P007015-P007490, at P007487-P007490).

392. In February 1995, the *Florida Infusion Chemo Net* reported that Glaxo was increasing the published AWP for Zofran®, but was specifically offering incentives to lower the actual price offered to medical providers, thereby allowing medical providers to seek reimbursement at inflated prices. Specifically:

Effective January 3, 1995. Glaxo has increased the acquisition costs of Zofran injection. The new AWP is set at \$233.02. However, the company has provided incentives to the market place which will ensure that Zofran price to physicians and clinics will be lower than the contractual price available prior to the increase.

Letter from Bliley, Chairman Commerce Committee to Nancy Min DeParle, Sept. 25, 2000 (P007015-P007490, at P007046).

393. Glaxo was fully aware that the larger spread for its product would be a big selling point. A flier in GSK's possession but produced by wholesaler NSS advertises to physicians that:

Your Zofran™ Deal Just Got Better!!!

(Effective 4:00pm January 9, 1995)

*New AWP \$233.02

New Price from NSS

** \$161.00 **

(GSK-MDL-ZN02-034942) (Highly Confidential).

394. In March 1996, Glaxo again increased the AWP for Zofran® by 4.8%. In response, SKB immediately increased the AWP for Kytril by 4.8%. An internal SKB memo, dated March 21, 1996, entitled "Kytril Price Increase," states:

I recommend a 4.8% price increase effective March 25, 1996 for all Kytril presentations. This is in response to a Glaxo Wellcome price increase of 4.8% for Zofran effective March 8, 1996.

(P007015-P007490, at P007078).

395. In a Glaxo internal memo dated October 25, 1994, entitled "Issue considerations on Zofran pricing strategies," Nancy Pekarek (a communications manager for Glaxo who later became Vice-President of U.S. Corporate Media Relations) recognized the implications of increasing the AWP to create a better spread:

If Glaxo chooses to increase the NWP and AWP for Zofran in order to increase the amount of Medicaid reimbursement for clinical oncology practices, we must prepare for the potential of a negative reaction from a number of quarters. Some likely responses:

(1) Press: Glaxo's health care reform messages stressed the importance of allowing the marketplace to moderate prices. On the surface, it seems that in response to the entrance of a competitor in the market, Glaxo has actually raised its price on Zofran—perhaps twice in one year. How do we explain that price increase on a drug that is already been cited in the press as one of, if not the most expensive drug on the hospital formulary?

If we choose to explain the price increase by explaining the pricing strategy, which we have not done before, then we risk further charges that we are cost shifting to government in an attempt to retain market share.

(2) Congress: Congress has paid a good deal of attention to pharmaceutical industry pricing practices and is likely to continue doing so in the next session. How do we explain to Congress an 8% increase in the NWP between January and November of 1994, if this policy is implemented this year? How do we explain a single 9% increase in the AWP? *What arguments can we make to explain to congressional watchdogs that we are cost-shifting at the expense of the government?* How will this new pricing structure compare with costs in other countries?

(3) *Private insurers, out-of-pocket payers: These groups, and perhaps others, are likely to incur greater costs as a result of this pricing strategy. How will they be affected? What response do we have for them?*

(GSK-MDL-Z01-05675) (Highly Confidential) (emphasis added).

396. Glaxo also knew that Zofran® products were being marketed based on the spread between the actual cost and the published AWP. For example, when Glaxo introduced the Zofran® premixed IV bag, it used marketing materials which stated:

Convenient
 Costs Less Than Vial
 Higher AWP
 Better Reimbursement

(P007015-007490, at P007243).

397. Other internal Glaxo documents directly compared the “Profit Per Dose” and “Profit as %” and “Profit Per Vial” of Zofran® to Kytril®. These comparisons also identified that in order to increase the spread for Zofran®, Glaxo included “early pay disc” and “rebates” and “incentive.”

398. In marketing the new Zofran® premixed IV bag, Glaxo produced and used a document entitled “Profit Maximization – It’s In the Bag.” This document compared Kytril® to Zofran® based upon its total return of investment (ROI). Specifically, Glaxo’s marketing materials including the following chart:

	Cost	AWP	Potential Reimbursement/Patient	Reimbursement/Year	ROI
Zofran 32mg bag	\$110.41	\$195.00	84.59	\$13,957,350	76.6%
Kytril 1 mg vial	\$102.73	\$175.00	72.27	\$11,924,000	70.3%

(P007114) (Highly Confidential).

399. Another Glaxo document entitled “Profit Maximization – Continued” reflects how much “Total Revenue Potential” there was for using Zofran® because of the large spread between the cost and reimbursement for various Zofran® products. (P007115) (Highly Confidential).

400. An internal SKB document further acknowledges Glaxo’s attempts to use and market the spread and its effects on the Class:

As of late, Glaxo promotional efforts have focused almost entirely on the financial benefits of “up-dosing” rather than efficacy of Zofran. ***Though physicians have certainly benefited financially from such tactics, it is costing 3rd party payers and patients more for medication.***

(P007115-P007490, at P007138-P007139) (Highly Confidential) (emphasis added).

401. In a September 27, 2000 article in *USA Today*, Glaxo spokesman Rick Sluder (who received a copy of the October 24, 1994 memo described herein) discussed the issue of the spread and blamed a system that set up a reimbursement method that relies on average wholesale prices which are not actually "representative of actual prices." Mr. Sluder, admitting that Glaxo changed its wholesale prices to keep up with competitors who changed wholesale prices, stated "We didn't want to put ourselves at a price disadvantage." Mr. Sluder also admitted that the marketing of Glaxo drugs is based, in part, on the spread. In fact, he noted that Glaxo's sales staff is briefed on the price advantages to doctors who bill and get reimbursed based upon the AWP. (E-mail from Clapton to Vaughan dated Sept. 27, 2000 citing "How Drug Makers Influence Medicare Reimbursements to Doctors; WALL STREET JOURNAL (P007501-P007506).

5. SKB's Kytril

402. According to its internal documents (and prior to selling Kytril®'s global rights to the Roche Group in December 2000), SKB also knew that by creating the spread for Kytril®, it could directly affect the amount of revenue medical providers receive and thereby affect overall demand for Kytril®. Specifically, an August 6, 1996 internal SKB memo stated:

In the clinic setting however, since Medicare reimbursement is based on AWP, product selection is largely based upon the spread between acquisition cost and AWP.

* * *

From this analysis, there seems to be no other reason, other than profitability, to explain uptake differentials between the hospital and clinic settings, therefore explaining why physicians are willing to use more expensive drug regimens.

(P007015-P007490, at P007249-P007250).

403. Internal SKB documents reveal how it marketed the spread. One internal document entitled "Price Comparison of Kytril and Zofran for Reimbursement" discussed how

much additional revenue and “spread per patient” a medical provider would make by using Kytril® due to its larger spread. It stated:

Kytril reimbursement for 5 patients treated \$540.00 - Kytril 6 treated patients \$423.12

Difference = \$117.00 every 6 patients.

Use 5ht3 5 times a day = \$2,340.00 month. \$28,080.00 year more!

(P007015-P007490, at P007117).

404. Other internal SKB documents entitled “Cost v. Profit” and “Kytril Profit Model” compare Kytril® and Zofran® to demonstrate how much additional profit/revenue the medical provider will receive by using Kytril®.

6. General Counsel Correspondence Between Glaxo and SKB

405. Most revealing is an exchange of correspondence between counsel for Glaxo and SKB over Zofran® and Kytril® in which each accuse the other of fraud.

406. On February 6, 1995, Timothy D. Proctor, Senior Vice President, General Counsel and Secretary for Glaxo, sent a letter to J. Charles Wakerly, Senior Vice President, Director and General Counsel of SKB informing him of “several issues pertaining to the advertising and marketing of Kytril”:

Glaxo’s sales representatives have encountered a substantial amount of what appear to be “homemade” Kytril vs. Zofran cost comparisons. It is our understanding that many of these pieces have been generated through a company-provided lap top computer program.

. . .

In addition, a significant number of these pieces (see Exhibits F-J) contain direct statements or make references as to how institutions can increase their “profits” from Medicare through the use of Kytril. Some even go so far as to recommend that the medical professional use one vial of Kytril for two patients (see Exhibit F) but charge Medicaid for three vials. This raises significant fraud and abuse issues which I am sure you will want to investigate.”

(P007015-P007490, at P007123-P007126).

407. On February 22, 1995, Ursualy B. Bartels, Vice President and Associate General Counsel for SKB, wrote in response that SKB was investigating Glaxo's claims and asked whether Glaxo had specific information regarding the improper marketing of Kytril. Mr. Bartels also accused Glaxo of using false and misleading marketing materials regarding Zofran that rely on the medical providers' ability to garner more profit. Specifically, he stated:

Regarding similar concerns, we would like to draw your attention to reports we are receiving from our field force regarding reimbursement issues. In an apparent effort to increase reimbursement to physicians and clinics, effective 1/10/95, Glaxo increased AWP for Zofran by 8.5%, while simultaneously fully discounting this increase to physicians. The latter was accomplished by a 14% rebate available to wholesalers on all non-hospital Zofran sales on the multi-dose vial. *The net effect of these adjustments is to increase the amount of reimbursement available to physicians from Medicare and other third party payors whose reimbursement is based on AWP.* Since the net price paid to Glaxo for the non-hospital sales of the Zofran multi-dose vial is actually lower, it does not appear that the increase in AWP was designed to increase revenue per unit to Glaxo. *Absent any other tenable explanation, this adjustment appears to reflect an intent to induce physicians to purchase Zofran based on the opportunity to receive increased reimbursement from Medicare and other third party payors. In fact, we have had numerous verbal reports from the field concerning Glaxo representatives who are now selling Zofran based on the opportunity for physicians to receive a higher reimbursement from Medicare and other third-party payors while the cost to the physician of Zofran has not changed.*

(P007015-007490, at P007478-P007481) (emphasis added).

408. On April 25, 1995, Adrianna L. Carter, Glaxo Assistant General Counsel, responded to SKB's February 22, 1995 letter. Ms. Carter provided, pursuant to SKB's request, numerous additional examples of false and misleading marketing materials concerning "cost comparisons distributed to health care professionals by SmithKline representatives." Ms. Carter also denied SKB's allegations regarding "fraud and abuse" over the price increase of Zofran. However, Ms. Carter did admit that the AWP price increase for Zofran® does not affect the

actual cost to medical providers and that Glaxo's sales representatives were using the "spread" to gain market share. Specifically, Ms. Carter stated:

It is true that, despite a price increase, some physicians and other healthcare professionals will not see the higher price as the result of rebates or other incentives.

* * *

It is also true that our sales representatives have been explaining the relationship between the price and Medicare reimbursement for Zofran to physicians.

* * *

Finally, Ms. Carter stated that despite SKB's assertions that any alleged improper marketing of Kytril would end, "Unfortunately, despite your efforts, these activities are still ongoing."

(P007015-007490, at P007127-P007131).

409. The fact that Glaxo and SKB each accused the other of similar conduct, but neither took any action to bring it to the attention of the public or the appropriate authorities, is evidence that each of them were engaged in an ongoing scheme to defraud the Plaintiffs and Class.

7. Other Improper Incentives

410. In addition to marketing the spread on its products, the GSK Group has also used other methods to induce physicians and other intermediaries to use its drugs such as rebates and free samples in order to increase the spread between acquisition costs and reimbursement.

411. In an e-mail by GSK account representative Paul J. Ostruszka explaining how he was able to increase the market share of Zofran over Anzimet, among the suggested techniques he recommends to his fellow GSK account reps is "Ask your customers how much JUST 1 FREE Zofran Tablet Sample is WORTH" (emphasis in original). This e-mail was later forwarded to the entire Zofran team. (GSK-MDL-ZN02-077634).

412. An advertisement in the *Florida Infusion Chemo net* reveals that SKB created the spread not only by artificially inflating the AWP for Kytril®, but also by providing discounts and rebates. Specifically, the advertisement states:

We have been notified that, effective April 1, 1995, SmithKline's long running promotional rebate for Kytril purchases will come to a very successful conclusion.

(P007015-007490, at P007187).

413. SKB also knew that medical providers were billing Plaintiffs and the Class for a 1 mg single dose vial per patient, but actually were using less than the full single dose per patient. Depending on the weight of a patient, medical providers were able to use less of the drug, *i.e.*, the lighter the patient, the less Kytril® was needed. SKB subsequently introduced a Kytril® 4 mg Multi-Dose vial that allowed medical providers to bill 6 treatments for the cost of 4. For example, an SKB marketing document entitled "Kytril Vial Usage" states, "You can use only three vials of Kytril for four patients." (P007015-007490, at P007068 and P007455).

414. SKB also used other financial incentives to decrease medical providers' costs and thereby increase profits. For example, SKB promised to contribute to research and education programs through the OnCare Foundation if OnCare agreed to use Kytril instead of a competing drug. (P007015-007490, at P007061).

8. Specific GSK Group AWPs Documented by the DOJ

415. In a report published by the DHHS (the "DHHS Report"), the DOJ documented that the published AWPs for various dosages of Zofran and Kytril manufactured by The GSK Group were substantially higher than the actual prices listed by wholesalers. The chart below sets forth the AWPs identified by the DOJ and the spread associated with one particular dosage of each drug. These figures compare the DOJ's determination of an accurate AWP for that particular dosage, based upon wholesalers' price lists, with the AWP reported by The GSK Group in the 2001 *Red Book*.

Drug	GSK 2001 <i>Red Book</i> AWP	DOJ Determined Actual AWP	Difference	Percentage Spread
Ondanestron (Zofran)	\$128.24	\$22.61	\$101.63	450%
Granisetron (Kytril)	\$195.20	\$139.04	56.16	40%

(P006299-P006316).

416. As set forth above, the GSK Group's scheme to inflate its reported AWPs and market the resulting spread to increase the market share of its drugs has resulted in excessive overpayments by Plaintiffs and the Class.

M. Hoffman-LaRoche

417. Hoffman-LaRoche engages in an organization-wide and deliberate scheme to inflate AWPs. Hoffman-LaRoche has stated fraudulent AWPs for all or almost all of its drugs, including, Kytril and CellCept. The specific drugs of Hoffman-LaRoche for which relief is sought in this case are set forth in Appendix A and are identified below:

Manufacturer	Brand Name (if applicable)	Generic Name	Therapeutic Category/Usage
HOFFMAN-LaROCHE	Cellcept	mycophenolate mofetil	Immunosuppressant Used to lower the body's natural immunity in patients who receive organ transplants
	Cellcept IV	mycophenolate mofetil hcl	Immunosuppressant Used to lower the body's natural immunity in patients who receive organ transplants
	Kytril	granisetron hcl	Antiemetic (Gastrointestinal Agent) Used to prevent the nausea and vomiting that may occur after treatment with anticancer medicines (chemotherapy) or with radiation therapy

1. Hoffman-LaRoche Controls the Published AWP for Its Products

418. Hoffman-LaRoche has controlled and set the AWPs for its pharmaceutical products through direct communications with industry compendia during the Class Period.

1. Inflated Hoffman-LaRoche AWPs From Hoffman LaRoche Price Lists

419. According to the information provided on Hoffman-LaRoche's own website, the published AWPs for Kytril and CellCept were higher than the actual prices provided to wholesalers.

2. Hoffman-LaRoche Provided Free Goods and Other Incentives

420. In addition to marketing the spread, Hoffman-LaRoche has utilized other impermissible inducements to stimulate sales of its drugs. These inducements were designed to result in a lower net cost to the provider while concealing the actual wholesale price beneath a high invoice price. By utilizing "off-invoice" inducements, Hoffman-LaRoche provided purchasers with substantial discounts meant to gain their patronage while maintaining the fiction of a higher wholesale price.

421. As set forth above, Hoffman-LaRoche's scheme to inflate its reported AWPs and market the resulting spread to increase the market share of its drugs and its use of other "off invoice" rebates and financial inducements to its customers has resulted in excessive overpayments by Plaintiffs and the Class.

N. Immunex

422. Immunex engages in an organization-wide and deliberate scheme to inflate AWPs. Immunex has stated fraudulent AWPs for all or almost all of its drugs, including those set forth below. The specific drugs of Immunex for which relief is sought in this case are set forth in Appendix A and are identified below:

Manufacturer	Brand Name (if applicable)	Generic Name	Therapeutic Category/Usage
IMMUNEX	Leukine	sagramostin	Antineutropenic Agent Used to help produce bone marrow and white blood cells
	Novantrone	mitoxane hydrochloride	Antineoplastic Used in the treatment of multiple sclerosis and various forms of cancer

Manufacturer	Brand Name (if applicable)	Generic Name	Therapeutic Category/Usage
	Thioplex	lyophilized thiopeta	Antineoplastic Used in the treatment of ovarian and breast cancer, lymphoma and bladder tumors
		leucovorin calcium	Antianemic Agent (Blood Modifier) Used in the treatment of anemia
		methotrexate sodium	Antineoplastic Used in the treatment of various forms of cancer

1. Immunex Has Been the Target of Government Investigations

423. In connection with its scheme to inflate AWPs, Immunex has been investigated by the United States Department of Justice, the Office of Inspector General of the Department of Health and Human Services, the Attorney General for the State of Texas, and the Attorney General for the State of California.

1. Immunex Definition and Understanding of AWP

424. Immunex's internal documents reveal that it understood how industry compendia defined and utilized AWPs:

Red Book Definition of AWP

The average wholesale price as we consider it here at Red Book is the price a retail hospital or pharmacy pays if purchases product from wholesaler before the discount if any.

Blue Book Definition of AWP

AWP represents an average price which a wholesaler would charge a pharmacy for a particular product.

(IAWP002238) (Highly Confidential).

2. Immunex Controls the Published AWP for its Products

425. Immunex controlled and set the AWPs for its pharmaceutical products through direct communications with industry compendia during the Class Period. In 2000, in the midst of numerous government investigations concerning AWP manipulation, Immunex denied

responsibility for controlling the published AWP for its products. For example, in an October 26, 2000 letter to *Red Book*, Immunex states in pertinent part:

As requested, enclosed please find an updated summary of list pricing and package information for Immunex products. Please note that Immunex Corporation is not responsible for setting the Average Wholesale Price (AWP). Therefore, we do not set or approve AWP information for any Immunex products.

(IAWP023473) (Highly Confidential). Previously, in a 1996 interview, an Immunex spokesperson had informed Barron's that "drug manufacturers have no control over the AWPs published." (IAWP003071) (*Hooked on Drugs*, Barron's, Jun. 10, 1996).

426. Immunex's internal documents, however, establish that it controlled the AWP for all of its products throughout the Class Period. For example:

a. A January 12, 1996 letter from *Red Book* to Immunex, in pertinent part, states:

This letter is a confirmation letter that we have received and entered your latest AWP price changes in our system.

(IAWP008102) (Highly Confidential).

b. A January 12, 1995 letter from Immunex to *Red Book* states:

Below you will find a list of new suggested Average Wholesale Prices (AWPs) for selected Immunex products, along with a new NDC ... all effective January 10, 1995 ... Please update your databases accordingly. A new copy of Immunex's Average Wholesale Price Product Pricing Guide will be sent to you next week.

(IAWP016500) (Highly Confidential).

3. Immunex's AWP Manipulation Benefited Providers at the Expense of the Class

427. The purpose of Immunex's manipulation was to increase the spread in order to maximize the profit to providers and other intermediaries at the expense of Plaintiffs and the

Class. Immunex understood that providers and intermediaries were reimbursed at AWP – and benefited from a larger spread.

a. In an internal document entitled “Health Care Policy Fast Facts,” created in 1995, Immunex urged its sales personnel to remember “[p]hysician’s offices use their own charge schedule for billing purposes, and get reimbursed at AWP, based on the published prices in the pricing databases.” (IAWP012961) (Highly Confidential).

b. Recently, in a January 3, 2000 interoffice memo, Immunex discussed the significant revenues to be made by providers which used its Leucovorin and Methotrexate products. Specifically, Immunex stated that, “Leucovorin and Methotrexate represent significant revenue sources for the physician office or clinic. Due to the ‘spread’ (difference between acquisition cost and AWP), physicians have reaped substantial profits.” (IAWP051149-52) (Highly Confidential).

428. Immunex, in a conscious effort to increase the spread for providers and intermediaries, changed its AWPs and marketing practices accordingly. In a February 21, 1997 internal memo discussing reimbursement on its products, in pertinent part, Immunex stated:

The following are the reimbursement schema for Leukine, Novantrone, Thioplex and Leucovorin:

Here’s the way it works [for Leukine] – the Red Book Price (AWP) for our 250 mcg is \$117.79 and \$221.71. **However**, payors take the \$117.79 and divide it by 5, now that we bill per 50 mcg increments. This is equal to \$23.56 per 50 mcg, hence reimbursement on a 500 mcg vial is \$235.60. We need to take into account that in some AOR markets they get AWP or AWP plus a percentage, in others, depending on the makeup of the patient population, they may only get the 80% Medicare allowable (\$188.48). So here’s what the spread looks like:

\$235.60 (AWP)	\$188.48
	(80% Medicare allowable)
-\$112.06 (AOR contract price)	-\$112.06
+\$123.54 per 500 mcg vial	\$76.42 (68% spread)
(110% spread)	

(IAWP008528) (Highly Confidential) (emphasis in original).

429. Immunex performed an analysis of competitive AWP pricing (IAWP003407-13) (Highly Confidential) and established a “Reimbursement Hotline” for a number of its products (IAWP016686-88) (Highly Confidential).

430. Immunex, through its employees and agents, also provided free samples of its drugs to customers. (IAWP005418) (Highly Confidential) The free samples would be used to offset the total cost associated with purchases of its drugs, thereby increasing the spread, while also concealing the actual cost of the drug from Plaintiffs and the Class.

4. Specific Immunex AWPs Documented by the DOJ

431. In a report published by the DHHS (the “DHHS Report”), the DOJ documented at least 7 instances where the published AWPs for various dosages of 2 drugs manufactured by Immunex were substantially higher than the actual prices listed by wholesalers. The chart below sets forth the 2 drugs identified by the DOJ and the spread associated with one particular dosage of each drug. These figures compare the DOJ’s determination of an accurate AWP for that particular dosage, based upon wholesalers’ price lists, with the AWP reported by Immunex in the 2001 *Red Book*.

Drug	2001 <i>Red Book</i> AWP	DOJ Determined Actual AWP	Difference	Percentage Spread
Leucovorin Calcium	\$137.94	\$14.58	\$123.36	846%
Methotrexate Sodium	\$20.48	\$7.10	\$13.38	188%

(P006299-P006316).

432. In a report published by DHHS in 1997, the Department undertook an analysis of the twenty drug codes that represented the largest dollar outlays to the Medicare Program and compared Medicare’s payments with the prices available to the physician and supplier communities. For mitoxantrone hydrochloride, sold by Immunex under the brand name Novantrone, the DHHS found that Medicare paid \$172.81, while the actual average wholesale

price was \$142.40, resulting in a spread of 21.36%. "Excessive Medicare Payments for Prescription Drugs" (Dec. 1997).

5. Inflated AWPs From Immunex Price Lists

433. In response to government subpoenas, Immunex produced numerous price lists setting forth spreads between AWPs and prices offered to wholesalers, providers and other intermediaries. A review of those price lists reveals that Immunex has consistently offered drugs and other solutions to its customers at prices significantly below the published AWP and that the spread was of great importance to its customers.

434. As set forth above, Immunex's scheme to inflate its reported AWPs and market the resulting spread to increase the market share of its drugs has resulted in excessive overpayments by Plaintiffs and the Class.

6. Immunex Concealed Its AWP Manipulation

435. Immunex deliberately acted to conceal its fraudulent reporting and marketing of the AWP spread. For example, under the guise of "simplifying" its product listings, on June 3, 1994, Immunex instructed the *Red Book* to "delete all references to Direct Price for all Immunex products, effective immediately" and confirmed that "only AWP (Average Wholesale Price) w[ould] be listed for [its] products[.]" (IAWP016524) (Highly Confidential). Immunex effectively hid the AWP spread from Plaintiffs and the Class.

O. The Johnson & Johnson Group (J&J, Centocor and Ortho)

436. The Johnson & Johnson Group engages in an organization-wide and deliberate scheme to inflate AWPs. The Johnson & Johnson Group has stated fraudulent AWPs for all or almost all of its drugs, including those set forth below. The specific drugs of the Johnson & Johnson Group for which relief is sought in this case are set forth in Appendix A, and are set forth below:

Manufacturer	Brand Name (if applicable)	Generic Name	Therapeutic Category/Usage
JOHNSON & JOHNSON GROUP (J&J, Janssen, McNeil, Ortho and	Aciphex	rabeprazole sodium	Gastric Acid Pump Inhibitor (Gastrointestinal Agent) Used in the treatment of gastroesophageal reflux disease and duodenal ulcers
Centocor)	Bicitra	sodium citrate & citric acid	Alkalizer Used in the prevention of kidney stones
	Duragesic	fentanyl	Analgesic Used in the treatment of chronic pain
	Elmiron	pentosan polysulfate sodium	Anti-Inflammatory Agent Used for relief of pain associated with interstitial cystitis
	Erycette	erythromycin	Antiacne Agent; Antibacterial Agent Used to help control acne
	Flexeril	cyclobenzaprine	Skeletal Muscle Relaxant (Analgesic) Used in the treatment of muscle spasm associated with musculoskeletal conditions
	Floxin	ofloxacin	Antibacterial Agent Used in the treatment of pneumonia, bronchitis, gonorrhea and certain other infections
	Grifulvin	griseofulvin microsize	Antifungal Agent Used to treat fungus infections of the skin, hair, fingernails, and toenails
	Haldol	haloperidol lactate	Antiemetic (Gastrointestinal Agent); Antipsychotic (Psychotherapeutic Agent) Used to treat nervous, mental, and emotional conditions
	Haldol Decanoate	haloperidol decanoate	Antiemetic (Gastrointestinal Agent); Antipsychotic (Psychotherapeutic Agent) Used to treat nervous, mental, and emotional conditions
	Levaquin	levofloxacin	Antibacterial Agent Used to treat bacterial infections in many different parts of the body
	Monistat	miconazole nitrate	Antifungal Agent Used in the treatment of yeast infections
	Mycelex	clotrimazole	Antifungal Agent Used in the treatment of candidiasis and tinea versicolor
	Pancrease	amylase-lipase-protease	Digestant; Enzyme, Pancreatic (Gastrointestinal Agent) Used in the treatment of gastrointestinal orders

Manufacturer	Brand Name (if applicable)	Generic Name	Therapeutic Category/Usage
	Parafon Fort	chlorzoxazone	Skeletal Muscle Relaxant (Analgesic) Used to relax certain muscles and relieve the pain and discomfort caused by strains, sprains, or other injuries to muscles
	Polycitra	potassium & sodium citrates w/ citric acid	Alkalizer Used in the prevention of kidney stones
	Procrit	epoetin alfa	Antianemic Used in the treatment of anemia in HIV-infected, cancer or chronic renal failure patients
	Regranex	becaplermin	Biological Response Modifier Used in the treatment of diabetic neuropathic ulcers
	Remicade	infliximab	Anti-Inflammatory Agent; Antirheumatic Agent Used to treat Crohn's disease and rheumatoid arthritis
	Reminyl	galantamine hydrobromide	Cholinesterase Inhibitor (Central Nervous System Agent) Used in the treatment of dementia of the Alzheimer's type
	Renova	tretinoin	Antiacne Agent Used for mitigation of fine wrinkles and other attributes of facial skin
	Retin-A	tretinoin	Antiacne Agent Used to treat acne
	Retin-A Micro	tretinoin microsphere	Antiacne Agent Used to treat acne
	Risperdal	risperidone	Antipsychotic Agent (Psychotherapeutic Agent) Used to treat the symptoms of psychotic disorders
	Spectazole	econazole nitrate	Antifungal Agent Used to treat infections caused by a fungus
	Sporanox	itraconazole	Antifungal Agent Used in the treatment of various fungal infections
	Terazol	terconazole vaginal	Antifungal Agent Used to treat yeast (fungus) infections of the vagina
	Testoderm	testosterone	Androgen; Antianemic Agent; Antineoplastic Used for replacement therapy in males with a deficiency or absence of testosterone

Manufacturer	Brand Name (if applicable)	Generic Name	Therapeutic Category/Usage
	Tolectin	tolmetin sodium	Antirheumatic Agent Used to relieve some symptoms caused by arthritis
	Topamax	topiramate	Anticonvulsant Used to help control some types of seizures in the treatment of epilepsy
	Tylox	acetaminophen w/ codeine	Analgesic Used to relieve pain.
	Tylenol with codeine		
	Ultracect	tramadol- acetaminophen	Analgesic Used to relieve pain
	Ultram	tramadol hcl	Analgesic Used for management of pain
	Urispas	flavoxate hydrochloride	Autonomic Nervous System Agent Used in the treatment of symptoms of various urologic disorders.
	Vascor	bepridil hcl	Antianginal Agent Used to relieve and control angina pectoris and hypertension

1. The Johnson & Johnson Group Has Been the Target of Government Investigations

437. In connection with its scheme to inflate AWPs, the Johnson & Johnson Group has been investigated by the General Accounting Office and the Office of the Attorney general for the Commonwealth of Massachusetts.

438. J&J's internal documents reveal that it was familiar with and understood how industry compendia defined and utilized AWPs. For example, in a rebate agreement between J&J and Merck-Medco Managed Care, Inc. dated December 19, 1996, the parties defined AWP as meaning "the average wholesale price as published in the most current version of either First Data Bank or the Red Book." (J&J000599) (Highly Confidential).

439. The Johnson & Johnson Group has engaged in an ongoing deliberate scheme to inflate AWPs and to market the spread to increase the sales of its products. In a report published by the GAO, federal investigations have documented fraudulently inflated AWPs reported for

epoetin alpha (sold by J&J as Procrit). J&J is identified in various annual *Red Book* publications as one of two sources for epoetin alfa. The other source for epoetin alfa is Defendant Amgen.⁷

440. In September 2001, the GAO reported that epoetin alfa accounted for the second highest percentage of Medicare expenditures on drugs in 1999, accounting for 9.5% of spending for prescription drugs by Medicare in 1999 and for 3.4% of all Medicare allowed services. These massive federal expenditures for epoetin alfa, caused by the J&J Group and Amgen's AWP scheme as well as the inflated cost to Plaintiffs and members of the Class, are even more outrageous given the fact that the research and development of epoetin alpha was originally underwritten by grants from the federal government.⁸

441. By way of further example, the J&J Group has deliberately overstated and continues to overstate the AWP for Remicade®. The published AWP for Remicade® continued to increase each year during the class period. For example, the AWP was listed as \$611.33 for a 100 mg vial of Remicade® as of November 1999, and rose to \$665.65 when listed in the 2001 edition of the *Red Book*. At the same time, J&J deliberately marketed and promoted the sale of Remicade® to physicians based on the availability of inflated payments made by Medicare, assuring them that they would make a significant profit from the purchase of Remicade® as a result of the spread between the actual price to physicians and reimbursement based on the published AWP.

442. The J&J Group created promotional materials and worksheets to allow them to market the spread between the published AWP and the actual selling price to doctors. For example, a publication accessible through Defendants' web sites entitled "Office-Based Infusion Guide" demonstrates Defendants' aggressive marketing of this spread, specifically noting that,

⁷ Amgen markets epoetin alfa for use in the treatment of dialysis patients while the right to market epoetin alfa for all other uses is licensed to Defendant J&J.

⁸ Epogen® and Procrit® are based on different uses of a patented process technology developed at Columbia University with support from grants from the NIH. Columbia licensed their technology to Amgen for Epogen® and to Johnson & Johnson for Procrit®. *NIH Response to the Conference Report Request for a Plan to Ensure Taxpayers' Interests are Protected*, Department Of Health And Human Services National Institutes Of Health, July 2001.

“[d]epending on reimbursement, office-based infusion may provide a financial impact to a physician’s practice.” Moreover, the “Financial Analysis” section of the guide includes a “REMICADE® (infliximab) Financial Impact Worksheet,” which enables doctors see in actual dollars how much additional revenue the use of Remicade® would bring to their practice.

443. As set forth above, the J&J Group’s scheme to inflate its reported AWPs and market the resulting spread to increase the market share of its drugs has resulted in excessive overpayments by Plaintiffs and the Class.

444. Set forth below in Table 1 are the contract prices (not already referenced above) included in a J&J contract price list (effective from April 1, 1997 through March 31, 1998) contained in a supply agreement with Managed Healthcare Associates, Inc. dated March 17, 1997 and the AWP published in the 1997 *Red Book*, and their associated AWP spread. (J&J000121-23) (Highly Confidential).

Table 1

Drug	Contract Price	AWP	\$ Diff AWP	% Spread
Procrit (epoetin alfa)	\$950.00 (4000 u/ml 25x1 ml vials)	\$1200	\$250	20.8%
Ultram (tramadol hcl)	\$53.97 (1x100 50 mg)	\$62.34	\$8.37	13.4%
Duragesic fentanyl transdermal)	\$44.94 (25M 25mcg/hr 1x5)	\$53.94	\$9	16.7%
Floxin (ofloxacin)	\$276.89 (1x100 btls 200 mg/case)	\$332.28	\$55.39	16.7%
Propulsid (cisapride)	\$56.62 (10mgx100)	\$67.96	\$11.34	16.7%
Risperdal (risperidone)	\$335.59 (3 mg 1x100)	\$402.72	\$67.13	16.7%
Topamax tiramate)	\$123.00 (100 mg 1x60)	\$147.60	\$24.6	16.7%

1. J&J Concealed Its AWP Manipulation

445. J&J deliberately acted to conceal its fraudulent reporting and marketing of the AWP spread. J&J routinely required that its customers keep secret the prices they were being charged for J&J drugs. (J&J001022; J&J000110; J&J001430; J&J001483).

P. Novartis

446. Novartis engages in an organization-wide and deliberate scheme to inflate AWPs.

Novartis has stated fraudulent AWPs for many of its drugs. The specific drugs of Novartis for which relief is sought in this case are set forth in Appendix A.

Manufacturer	Brand Name (if applicable)	Generic Name	Therapeutic Category/Usage
NOVARTIS	Clozaril	clozapine	Antipsychotic (Psychotherapeutic Agent) Used to treat schizophrenia
	Combipatch	estradiol & norethindrone acetate	Hormone Used to treat symptoms of menopause
	Comtan	entacapone	Antidyskinetic Agent Used in combination with levodopa/carbidopa to treat Parkinson's
	Estraderm	estradiol	Antineoplastic; Hormone Used to relieve signs of menopause
	Exelon	rivastigmine tartrate	Cholinesterase Inhibitor (Central Nervous System Agent) Used to treat the symptoms of mild to moderate Alzheimer's disease
	Femara	letrozole	Antineoplastic Used to treat certain types of breast cancer in women
	Lamisil	terbinafine hcl	Antifungal Agent Used to treat fungus infections of the scalp, body, groin, feet, fingernails, and toenails
	Lamprene	clofazimine	Antibacterial Agent Used to treat leprosy
	Lescol	fluvastatin sodium	HMG-CoA Reductase Inhibitor (Cardiovascular Agent) Used to lower levels of cholesterol and other fats in the blood
	Lotensin	benazepril hcl	ACE Inhibitor (Cardiovascular Agent) Used to treat hypertension
	Lotensin HCT	benazepril & hctz	ACE Inhibitor (Cardiovascular Agent) Used to treat hypertension
	Lotrel	amlodipine besylate-benazepril hcl	ACE Inhibitor (Cardiovascular Agent) Used to treat hypertension
	Miacalcin	calcitonin (salmon)	Calcitonin (Hormone) Used to treat Paget's disease of bone. Also used to prevent continuing bone loss in women with postmenopausal osteoporosis and to treat hypercalcemia

Manufacturer	Brand Name (if applicable)	Generic Name	Therapeutic Category/Usage
	Parlodel	bromocriptine mesylate	Antidyskinetic Agent; Antihyperprolactinemic; Growth Hormone Suppressant Used to treat certain menstrual problems or to stop milk production. Also used to treat infertility and Parkinson's disease
	Ritalin	methylphenidate hcl	Central Nervous System Stimulant Used to treat attention-deficit hyperactivity disorder (ADHD) and narcolepsy
	Starlix	nateglinide	Antidiabetic Agent Used to treat a type of diabetes mellitus (sugar diabetes) called type 2 diabetes
	Tegretol	carbamazepine	Anticonvulsant; Antipsychotic (Psychotherapeutic Agent) Used to control some types of seizures in the treatment of epilepsy
	Trileptal	oxcarbazepine	Central Nervous System Agent; Anticonvulsant Used in the treatment of partial seizures
	Vivelle	estradiol	Antineoplastic; Hormone Used to relieve signs of menopause
	Vivelle-DOT	estradiol	Antineoplastic; Hormone Used to relieve signs of menopause

1. Novartis Has Been the Target of Government Investigations

447. In connection with its scheme to inflate AWPs, Novartis has been investigated by the Office of Inspector General of the Department of Health and Human Services. The Office of the Inspector General published a report for the Department of Health and Human Services in 2000 documenting Novartis' inflated AWP for Aredia, its brand of pamidronate disodium.

1. Inflated Novartis AWPs From Novartis Price Lists

448. As set forth above, Novartis' scheme to inflate its reported AWPs and market the resulting spread to increase the market share of its drugs has resulted in excessive overpayments by Plaintiffs and the Class.

Q. Pfizer

449. Pfizer engages in an organization-wide and deliberate scheme to inflate AWPs and has stated fraudulent AWPs for many of its drugs. The specific drugs of Pfizer for which relief is sought in this case are set forth in Appendix A, and are identified below:

Manufacturer	Brand Name (if applicable)	Generic Name	Therapeutic Category/Usage
PFIZER	Accupril	quinapril hcl	ACE Inhibitor (Cardiovascular Agent) Used in the treatment of hypertension
	Cardura	doxazosin mesylate	Autonomic Nervous System Agent Used to treat hypertension and benign prostatic hypertrophy
	Estrostep FE	norethindrone-ethynodiol-fe	Oral Contraceptive Also used in the treatment of acne
	Femhrt 1/5	ethynodiol-drostanolone acetate	Estrogen Combination (Hormone) Used in the treatment of menopause and prevention of postmenopausal osteoporosis
	Lipitor	atorvastatin calcium	Antilipemic Agent (Cardiovascular Agent) Used to lower cholesterol
	Nardil	phenelzine sulfate	Antidepressant (Psychotherapeutic Agent) Used in the treatment of depression
	Neurontin	gabapentin	Anticonvulsant Used in the treatment of epilepsy
	Zithromax	azithromycin	Macrolide Antibiotic Agent (Anti-Infective Agent) General antibiotic
	Zoloft	sertraline hcl	Serotonin Reuptake Inhibitor (Psychotherapeutic Agent: Antidepressant) Used in the treatment of depression
	Zyrtec	cetirizine hcl	Antihistamine Used in the treatment of allergic rhinitis

450. Pfizer manufactures and distributes some of the nation's most popular and highest selling brand name drugs.

451. Historically, Pfizer almost never changes the "spread" between the posted AWP and posted WAC for a Pfizer brand name product. Once initially launched, a Pfizer brand name product continues to bear the same difference between the posted AWP and the posted WAC (e.g., 16 2/3%, or 20%, or sometimes 25%).

452. In January 2002, Pfizer announced a prescription drug discount card that would be available to elderly and poor consumers along eligibility criteria similar to that of other discount cards.

453. At the same time, January 2002, Pfizer secretly increased the AWP/WAC spread to 25% for *all* of its brand name drugs. If a drug theretofore had a posted AWP/WAC spread of 20%, it was increased to 25% (something which Pfizer, and indeed all other drug companies, almost never do). If a Pfizer brand name drug already had had a 25% AWP/WAC spread, it remained so.

454. By doing so, Pfizer knew that the purpose and effect of these new listings would be to increase reimbursement payments by end payors by amounts that would be greater than actual transaction costs for other participants in the distribution chain (*i.e.*, wholesalers, distributors, pharmacies and PBMs). Also in doing so, Pfizer knew that the posted AWPs for many of their brand name drugs would become more misrepresentative of actual average wholesale prices given that the increased AWP/WAC spread bore no relation to actual transaction cost changes occurring in the marketplace.

455. Pfizer has been investigated by the Office of the Inspector General of the Department of Human Health Services and has entered into a \$49 million settlement arising from illegal practices with respect to Lipitor. OIG-HSS found that Pfizer has been providing unrestricted educational grants and rebates that were in fact discounts off the purchase price of Lipitor. Pfizer concealed these discounts from states who were entitled to receive the “best price” for Lipitor.

456. The provision of educational grants and rebates on Lipitor also had the effect of inflating the reported AWP.

457. On information and belief, based in part due to the substantial nature of the spreads between AWP and WAC identified in Appendix A, Pfizer has inflated its AWP on other drugs at issue.

R. The Pharmacia Group (Pharmacia and P&U)

458. The Pharmacia Group engages in an organization-wide and deliberate scheme to inflate AWPs. The Pharmacia Group has stated fraudulent AWPs for all or almost all of its drugs, including those set forth below. The specific drugs of The Pharmacia Group for which relief is sought in this case are set forth in Appendix A, and are set forth below:

Manufacturer	Brand Name (if applicable)	Generic Name	Therapeutic Category/Usage
PHARMACIA GROUP (Pharmacia and P&U)	Adriamycin	doxorubicin hydrochloride	Antineoplastic Used in the treatment of various forms of cancer
	Adrucil	fluorouracil	Antimetabolite; Antineoplastic Used in the treatment of various forms of cancer
	Amphocin	amphotericin b	Antifungal (Anti-Infective Agent) Used in the treatment of serious fungal infections
	Celebrex	celecoxib	Analgesic; Antirheumatic Agent Used to relieve some symptoms caused by arthritis
	Cleocin-T	clindamycin phosphate (topical)	Antibacterial Agent (Anti-Infective Agent) Used to treat bacterial infections
	Cytosar-U	cytarabine	Antineoplastic Used in the treatment of cancer of the blood
	Depo-Testosterone	testosterone cypionate	Androgen (Hormone) Used to replace hormones or stimulate growth
	Neosar	cyclophosphamide	Alkylating Agent (Antineoplastic) Used in the treatment of various forms of cancer as well as some kidney disease
	Solu-Cortef	hydrocortisone sodium succinate	Anti-Inflammatory Agent; Skin and Mucous Membrane Agent Used to provide relief for inflamed areas of the body. Also used as replacement therapy in adrenocortical insufficiency

Manufacturer	Brand Name (if applicable)	Generic Name	Therapeutic Category/Usage
	Solu-Medrol	methylprednisolone sodium succinate	Anti-Inflammatory Agent Used to provide relief for inflamed areas of the body. Also used as replacement therapy in adrenocortical insufficiency
	Toposar	etoposide	Antineoplastic Used in the treatment of testicular and lung cancer
	Vincasar	vincristine sulfate	Antineoplastic Used in the treatment of various forms of leukemia and cancer
		bleomycin sulfate	Antineoplastic; Antibiotic Agent (Anti-Infective Agent) Used in the treatment of various forms of cancer

1. The Pharmacia Group Has Been the Target of Government Investigations

459. In connection with its scheme to inflate AWPs, The Pharmacia Group has been investigated by the Department of Justice, the Texas Attorney General, the California Attorney General, the Massachusetts Attorney General, the Attorney General of the State of Connecticut, the Attorney General of the State of New York, and the Department of Health and Human Services Office of Inspector General.

1. Pharmacia's Definition and Understanding of AWP

460. Pharmacia understands that third party reimbursement is based on its published AWPs. According to a "Strategic Presentation on Average Wholesale Price (AWP)" prepared by P&U, the "Definition of AWP" is:

An artificial pricing index that is used as a common basis for third-party reimbursement to pharmacists and physicians.

-The difference between the published AWP (less a percentage) and the direct price is the profit margin that drives these classes of trade.

(PH 025785) (Highly Confidential). During this same presentation, Pharmacia provided an "AWP History":

- ◆ Historically, Wholesalers viewed AWP as an actual average selling price to their customers.
- ◆ Competition of 1980's led to AWP representing a "Suggested List Price"
- ◆ P&U AWP = 125% of Direct Price (DP)
- ◆ Exceptions being VANTIN, CVC, GENOTROPIN, and RESCRIPTOR = 120% of DP

(PH025791) (Highly Confidential). Further, the presentation recognized that "95 Medicare (Part B) outpatient drug bill (I.V./inhalants/oncolitics/nutritionals) of \$1.8 billion based primarily on AWP." (PH025793) (Highly Confidential).

2. The Pharmacia Group Controls the Published AWP for Its Products

461. The Pharmacia Group has controlled and set the AWPs for its pharmaceutical products through direct communications with industry compendia during the Class Period. In its presentation entitled "Strategic Presentation on Average Wholesale Price (AWP)," P&U included a flow chart that shows P&U communicates its AWPs to First Data Bank, Medi-Span and *Red Book*. This same flow chart then shows that third party payors rely on these industry compendia for prices. (PH025792) (Highly Confidential).

3. The Pharmacia Group's AWP Manipulation Benefited Providers at the Expense of the Class

462. The Pharmacia Group has engaged in an ongoing deliberate scheme to inflate AWPs. According to one member of the Congressional Ways and Means Committee:

The evidence . . . indicates that [Pharmacia & Upjohn] have knowingly and deliberately inflated their representations of the average wholesale price ("AWP"), wholesale acquisition cost ("WAC") and direct price ("DP") which are utilized by the Medicare and Medicaid programs in establishing drug reimbursements to providers.

* * *

[T]hese practices must stop and . . . these companies must return the money to the public that is owed because of their abusive practices.

See Extension of Remarks of U.S. Representative Pete Stark in the House of Representatives, October 3, 2000 (P007545-P007547).

463. In a letter dated October 3, 2000 to Pharmacia (with accompanying exhibits), Representative Stark addressed the Pharmacia Group's illegal practices:

The manipulated disparities between your company's reported AWPs and DPs are staggering. For example, in 1997, Pharmacia & Upjohn reported an AWP of \$946.94 for 200 mg. of Adriamycin PFS while offering to sell it to American Oncology Resources (AOR) for \$168.00 and to Comprehensive Cancer Center for \$152.00 (Composite Exhibit "1"). Your company then aggressively marketed its cancer drugs to health care providers by touting financial inducements and other types of incentives. Pharmacia & Upjohn created and marketed the financial inducements for the express purpose of influencing the professional judgment of doctors and other health care providers in order to increase the company's market share.

* * *

Pharmacia & Upjohn's own internal documents . . . reveal that the company abused its position as a drug innovator in an initial *Phase III* FDA clinical trial for a cancer drug used to treat lymphoma (Composite Exhibit "2") (emphasis in original).

" . . . Clinical Research Trials

Initial Phase III Protocol trial for "Oral Idamycin" in lymphomas. This trial will offer AOR \$1.1M [million] in additional revenues. Two hundred twenty-five (225) patients at \$5,000 per patient . . . (emphasis added by Rep. Stark)

The above . . . items are contingent on the signing of the AOR Disease Management Partner Program. AOR's exclusive compliance to the purchase of the products listed in the contract product attachment is also necessary for the above items to be in effect."

The linking of doctor participation in FDA clinical drug trials to their purchase and administration of profit-generating oncology drugs is entirely inconsistent with the objective scientific testing that is essential to the integrity of the trial.

* * *

It is clear that Pharmacia & Upjohn targeted health care providers, who might be potential purchasers, by creating and then touting the windfall profits arising from the price manipulation. For example, Pharmacia & Upjohn routinely reported inflated average wholesale prices for its cancer drug Bleomycin, 15u, as well as direct prices. The actual prices paid by industry insiders was in many years less than half of what Pharmacia & Upjohn represented. Pharmacia & Upjohn reported that the average wholesale price for Bleomycin, 15u, rose from \$292.43 to \$309.98, while the price charged to industry insiders fell by \$43.15 (Composite Exhibit "4").

* * *

Pharmacia & Upjohn reported price increases in October 1997 with full knowledge that the true prices of the drugs were falling. For example, Composite Exhibit "7" reveals that Pharmacia & Upjohn voluntarily lowered its price of Adriamycin PFS 200 mg to \$152.00 while reporting an AWP of \$946.94:

"Dear Willie,

A (VPR) Voluntary Price Reduction will become effective May 9, 1997. The wholesalers have been notified, however it may take two weeks to complete the transition . . ."

Additionally, internal Pharmacia & Upjohn documents secured through the Congressional investigations show that Pharmacia & Upjohn also utilized a large array of other inducements to stimulate product sales. These inducements, including "educational grants" and free goods, were designed to result in a lower net cost to the purchaser while concealing the actual price beneath a high invoice price. Through these means, drug purchasers were provided substantial discounts that induced their patronage while maintaining the fiction of a higher invoice price – the price that corresponded to reported AWPs and inflated reimbursements from the government. Composite Exhibit "8" highlights these inducements:

AOR/PHARMACIA & UPJOHN PARTNERSHIP PROPOSAL:
Medical Education Grants. A \$55,000 grant has been committed for 1997 for the AOR Partnership for excellence package including Education/Disease Management, Research Task Force, AOR Annual Yearbook. A \$40,000 grant to sponsor the AOR monthly teleconference. This sponsorship was committed and complete in February 1997 . . .

PHARMACIA & UPJOHN, INC. INTEROFFICE MEMO:
If needed, you have a "free goods" program to support your efforts against other forms of generic doxorubicin . . .

Use your “free goods” wisely to compete against other generic forms of Adriamycin, not to shift the customer to direct shipments. The higher we can keep the price of Adriamycin, the easier it is for you to meet your sales goals for Adriamycin (emphasis added by Rep. Stark).

(P007613-P007632).

464. Pharmacia’s marketing pitches, as quoted by U.S. Rep. Pete Stark in a September 28, 2000 letter to Alan F. Holmer, President of the Pharmaceutical Research and Manufacturers of America, promoted a physician’s ability to profit at the expense of Medicare and its beneficiaries:

PHARMACIA: Some of the drugs on the multi-source list offer you savings of over 75% below list price of the drug. For a drug like Adriamycin, the reduced pricing offers AOR a reimbursement of over \$8,000,000 profit when reimbursed at AWP. The spread from acquisition cost to reimbursement on the multi-source products offered on the contract give AOR a wide margin for profit.

(P007548-P007588).

465. In 1997, Pharmacia sent to a clinic a proposal listing the AWP and the contract price at which several drugs would be sold to the provider. The differences are staggering and just a few are noted below:

Drug	AWP	Suggested New Contract Price
Adriamycin (10 mg)	46.00	7.50
Adriamycin (50 mg)	230.00	37.50
Neosar (2 g)	86.00	18.00
Toposar (1 g)	1,330.75	120.00
Vincasar (2 mg)	741.50	7.50

(P007615).

4. Specific Pharmacia AWPs Documented by the DOJ

466. In a report published by the DHHS, the DOJ documented at least 43 instances where the published AWPs for various dosages of drugs manufactured by The Pharmacia Group

were substantially higher than the actual prices listed by wholesalers. The chart below sets forth the drugs identified by the DOJ and the spread associated with one particular dosage of each drug. These figures compare the DOJ's determination of an accurate AWP for that particular dosage, based upon wholesalers' price lists, with the AWP reported by The Pharmacia Group in the 2001 *Red Book*.

Drug	The Pharmacia Group's 2001 <i>Red Book</i> AWP	DOJ Determined Actual AWP	Difference	Spread
Amphotericin B	\$36.26	\$16.00	\$20.26	127%
Bleomycin Sulfate	\$309.98 ⁹	\$158.67	\$151.31	96%
Clindamycin Phosphate	\$93.60	\$61.20	\$32.40	53%
Cyclophosphamide	\$6.29	\$3.92	\$2.37	60%
Cytarabine	\$8.98	\$4.06	\$4.92	122%
Doxorubicin HCL	\$1104.13	\$150.86	\$953.27	632%
Etoposide	\$157.65	\$9.47	\$148.18	1,565%
Fluorouracil	\$3.20	\$1.47	\$1.73	118%
Hydrocortisone Sodium Succinate	\$2.00	\$1.55	\$.45	29%
Metholprednisolone Sodium Succinate	\$2.05	\$1.45	\$.60	41%
Testosterone Cypionate	\$17.01	\$11.79	\$5.22	44%
Vincristine Sulfate	\$43.23	\$5.10	\$38.13	748%

467. In OIG report OEI-03-00-00310, the government noted that 20 mg of irinotecan, which according to the *Red Book* is manufactured only by The Pharmacia Group, had a Medicare Median of \$117.81 and a Catalog Median of \$98.63, resulting in a spread of 19.45%. (P006398-P006424).

468. The GAO issued a report entitled "Payments for Covered Outpatient Drugs Exceed Providers' Cost" (GAO-01-1118) wherein it found that irinotecan had an Average AWP

⁹ Calculation based on the AWP listed in the 2000 *Red Book*.

of \$141.32, the Average Widely Available Discount from AWP to physicians for irinotecan was 22.9%, and the drug constituted 2.0% of the total amount of Medicare spending in 1999. (P005546-P005578).

469. As of April 2000, another Pharmacia Group drug, Toposar® (etoposide), had an AWP of \$28.38. The DOJ found that retailers were buying it for \$1.70. (P006299-006316).

470. Similarly, by letter dated September 25, 2000 to the HCFA Administrator, the Chairman of the Commerce Committee revealed that:

[I]n 1998, Pharmacia-Upjohn's Bleomycin had an AWP of \$309.98, but health care providers could purchase it for \$154.85. In 1997, Pharmacia-Upjohn's Vincasar could be purchased for \$7.50, while the AWP was a staggering \$741.50.

See letter dated May 25, 2000 from U.S. Rep. Thomas J. Bliley to Nancy-Ann Min DeParle, HCFA Administrator. (P007015-P007490).

471. Exhibit 1 to U.S. Rep. Pete Stark's September 28, 2000 letter to Alan F. Holmer, President of the Pharmaceutical Research and Manufacturers of America, reveals that while the AWP for 1 mg of Vincasar® (vincristine sulfate) was \$370.75 in 1997, one physician group's (American Oncology Resources) price in 1997 was only \$4.15. (P007515). Similarly, while the AWP for 2 mg of Vincasar® was \$741.50, AOR's actual pre-April 1997 price was \$7.75 (in fact, The Pharmacia Group had offered to reduce it to \$7.50). *Id.* As of April 2000, Adriamycin had a reported AWP of \$241.36, while the real wholesale price was \$33.43.

5. Inflated Pharmacia AWPs From Pharmacia's Price Lists

472. According to Pharmacia's own documents, the published AWPs for its drugs were higher than the actual prices provided to wholesalers. In response to government subpoenas, the Pharmacia Group produced numerous price lists setting forth spreads between AWPs and prices apparently offered to wholesalers, providers and other intermediaries. A review of those price lists reveals that Pharmacia has consistently offered hundreds of its drugs and other solutions to its customers at prices significantly below the published AWP and that the spread was of great

importance to its customers. To repeat every one of those drugs and the spread offered to each specific customer here is not practical. However, set forth below in Table 1 are a number of those drugs with spreads between the AWPs and direct prices. Table 1 is an analysis of certain dosages of P&U drugs from a document entitled "Oncology Express CONTRACT PRICING" (PH011977) (Highly Confidential).

Table 1

PRODUCT	LIST	AWP	CONTRACT PRICE	DIFFERENCE (between AWP and contract price)	PERCENTAGE SPREAD
Adriamycin	883.80	1104.13	119.00	985.13	828%
Adrucil	12.83	16.04	4.56	11.48	252%
Amphocin	29.01	36.26	13.00	23.26	179%
Neosar	80.22	100.28	16.15	84.13	521%
Toposar	614.81	768.51	33.84	734.67	2,171%

6. The Pharmacia Group Provided Free Goods and Other Incentives

473. In addition to marketing the spread, The Pharmacia Group has utilized other impermissible inducements to stimulate sales of its drugs. These inducements were designed to result in a lower net cost to the provider while concealing the actual wholesale price beneath a high invoice price. By utilizing "off-invoice" inducements, The Pharmacia Group provided purchasers with substantial discounts meant to gain their patronage while maintaining the fiction of a higher wholesale price.

474. The government investigators also uncovered an October 3, 1996 internal memorandum wherein Pharmacia told three oncology sales representatives:

Our competitive intelligence tells us that our pricing on Adriamycin, although higher than generics, is in the "ball park" for you to attain the customers Adriamycin business. If needed, you have a "free goods" program to support your efforts against other forms of generic doxorubicin.

. . . .

You should not have to use "free goods" to steer customer [sic] away from NSS or OTN. OTN and NSS Adriamycin pricing is competitive. Use your "free goods" wisely to compete against

other generic forms of Adriamycin, not to shift the customer to direct shipments. The higher we can keep the price of Adriamycin, the easier it is for you to meet your sales goals for Adriamycin.

(PH 024315).

475. As set forth above, The Pharmacia Group's scheme to inflate its reported AWPs and market the resulting spread to increase the market share of its drugs and its use of other "off invoice" rebates and financial inducements to its customers has resulted in excessive overpayments by Plaintiffs and the Class.

S. The Schering-Plough Group (Schering-Plough and Warrick)

476. The Schering Plough Group engages in an organization-wide and deliberate scheme to inflate AWPs. The Schering Plough Group has stated fraudulent AWPs for all or almost all of its drugs, including those set forth below. The specific drugs of The Schering Plough Group for which relief is sought in this case are set forth in Appendix A, and are set forth below:

Manufacturer	Brand Name (if applicable)	Generic Name	Therapeutic Category/Usage
SCHERING-PLOUGH GROUP	Clarinex	desloratadine	Antihistamine Used to relieve the symptoms of hay fever and hives of the skin
(Schering-Plough and Warrick)	Claritin	loratadine	Antihistamine Used to relieve or prevent the symptoms of asthma
	Claritin-D	loratadine & pseudoephedrine	Antihistamine Used to treat the nasal congestion, sneezing, and runny nose caused by colds and hay fever
	Diprolene	aug betamethasone dipropionate	Antipruritic (Skin & Mucous Membrane Agent) Used to help relieve redness, swelling, itching, and discomfort of many skin problems
	Diprosone	betamethasone dipropionate	Antipruritic (Skin & Mucous Membrane Agent) Used to help relieve redness, swelling, itching, and discomfort of many skin problems
	Elocon	mometasone furoate	Antipruritic (Skin & Mucous Membrane Agent) Used to help relieve redness, swelling, itching, and discomfort of many skin problems
	Eulexin	flutamide	Antineoplastic Used to treat cancer of the prostate gland

Manufacturer	Brand Name (if applicable)	Generic Name	Therapeutic Category/Usage
	Integrilin	eptifibatide	Cardiovascular Agent Used in the treatment of patients with acute coronary syndrome
	Intron-A	interferon alfa-2b	Immunomodulator Used in the treatment of hairy cell leukemia and chronic hepatitis B or C.
	Lotrisone	clotrimazole w/ betamethasone	Antifungal Agent (Anti-Infective Agent) Used to treat fungus infections
	Nasonex	mometasone furoate (nasal)	Anti-Inflammatory Agent (Nasal Preparation) Relieve the stuffy nose, irritation, and discomfort of hay fever and other allergies
	Peg-INTRON	peginterferon alfa-2b	Biological Response Modifier Used to treat chronic hepatitis C
	Proventil	albuterol sulfate	Bronchodilator (Respiratory Agent) Used to treat the symptoms of asthma, chronic bronchitis, emphysema, and other lung diseases
	Rebetol	ribavirin	Biological Response Modifier Used to treat hepatitis C
	Sebizon	sulfacetamide sodium	Anti-Infective Agent Used in the treatment of conjunctivitis and other ocular infections
	Temodar	temozolomide	Antineoplastic Used to treat a specific type of cancer of the brain in adults whose tumors have returned
	Trinalin Rep	azatadine & pseudoephedrine	Antihistamine Used to treat the nasal congestion, sneezing, and runny nose caused by colds and hay fever.
	Vanceril	beclomethasone (nasal)	Anti-Inflammatory Agent; Antiasthmatic Used to help prevent the symptoms of asthma
		albuterol	Bronchodilator (Respiratory Agent) Used for relief of bronchospasm in asthma sufferers
		clotrimazole	Antifungal Agent (Anti-Infective Agent) Used to treat yeast (fungus) infections of the vagina
		griseofulvin ultramicrocrystalline	Antifungal Agent (Anti-Infective Agent) Used to treat fungus infections of the skin, hair, fingernails, and toenails
		oxaprozin	Central Nervous System Agent; Antipyretic (Analgesic) Used in the treatment of osteoarthritis and rheumatoid arthritis

Manufacturer	Brand Name (if applicable)	Generic Name	Therapeutic Category/Usage
		perphenazine	Antiemetic (Gastrointestinal Agent); Antipsychotic Agent (Psychotherapeutic Agent) Used to treat serious mental and emotional disorders. Also used to relieve moderate to severe pain in some hospitalized patients
		potassium chloride	Electrolytic Agent Used to prevent and treat potassium deficit secondary to diuretic or corticosteroid therapy
		sodium chloride	Flush; Abortifacient Used to remove medicine and blockage from intravenous (IV) catheter. Also used to induce abortion
		sulcrafate	Gastrointestinal agent Used for short term treatment of duodenal ulcer
		theophylline er	Bronchodilator (Respiratory Agent) Used to treat and/or prevent the symptoms of bronchial asthma, chronic bronchitis, and emphysema

1. The Schering Plough Group Has Been the Target of Government Investigations

477. In connection with its scheme to inflate AWPs, The Schering Plough Group has been investigated by the Department of Justice, Texas Attorney General, West Virginia Attorney General, California Attorney General, California Bureau of Medi-Cal Fraud and Elder Abuse, and the Department of Health and Human Services Office of Inspector General, and the U.S. Attorney for the District of Massachusetts.

478. On May 30, 2003, Schering Plough announced that the U.S. Attorney for the District of Massachusetts had advised that its subsidiary, Schering Corporation, is the subject of a federal grand jury investigation. Schering Plough is the target of a criminal investigation involving: (i) providing remuneration, such as drug samples, to providers to induce the purchase of Schering products for which payment was made through federal health care programs; (ii) selling misbranded or unapproved drugs; (iii) submitting false wholesale pricing information for its pharmaceutical products to the government; and (iv) destroying evidence and obstructing

justice relating to the government's investigation. *See* Schering Plough Press Release dated May 30, 2003, located at <http://www.sch-plough.com/news/2003/business/20030530.html>; "Schering Plough expects indictment," The Philadelphia Inquirer, at C3 (May 31, 2003). Moreover, according to Schering Plough's Form 10-K for the year 2000, this investigation has focused on "whether the AWP set by pharmaceutical companies for certain drugs improperly exceeds the average prices paid by dispensers . . . and other pricing and/or marketing practices."

479. A Medicaid investigation by the Texas Attorney General revealed that The Schering-Plough Group defrauded the State of Texas \$14.5 million. Investigators determined that The Schering-Plough Group provided the greatest "spread" amongst the drug companies selling albuterol in Texas, and thereby obtained the largest market share for albuterol. The Schering-Plough Group sold a box of albuterol to pharmacies for \$13.50, while it charged the Texas Medicaid program \$40.30, a 200% increase. *See Cornyn Sues Three Drug Companies for Medicaid Fraud*, Press Release by the Office of the Attorney General, State of Texas, Sept. 7, 2000. (www.oag.state.tx.us.gov)

480. On October 11, 2001, the West Virginia Attorney General filed suit against Warrick, alleging that Warrick defrauded state agencies and citizens by deliberately overstating the AWP for certain drugs, including albuterol, from approximately 1995 until December 2000.

1. The Schering Plough Group Controls the Published AWP for Its Products

481. The Schering Plough Group has controlled and set the AWPs for its pharmaceutical products through direct communications with industry compendia during the Class Period. For example, on February 23, 1995, Warrick sent a letter to First Data Bank, stating:

Effective Friday, February 24, 1995, at 5:00 p.m., the price of Warrick Albuterol Solution 0.5% 20ml will increase as follows:

NDC	<u>59930-</u>	<u>AWP</u>
Albuterol Solution 0.5% 20 ml	1515-04	\$13.95

(WAR0024086) (Highly Confidential).

2. The Schering Plough Group's AWP Manipulation Benefited Providers at the Expense of the Class

482. A Schering Laboratories memorandum dated May 20, 1993 demonstrates Defendant's recognition that intermediaries choose drugs based on favorable AWP spreads. At the generic launch of albuterol, Schering stated:

Proventil will stay listed at AWP; therefore, Proventil is a favored product for third party reimbursement that provides for the AWP minus 10% reimbursement rate to chains. Thus, they can buy off the Proventil deal and bill at AWP.

(WAR005419-20) (Highly Confidential).

483. According to Warrick's own documents, Warrick consistently maintained a spread between the AWPs and the direct prices it offered for its albuterol products. For example, a "Price Change" alert dated June 7, 1999 sent to Warrick customers provides:

Product	Pkg. Size	NDC <u>59930</u>	AWP	Direct Price
Albuterol Inhalation Aerosol	17 g	1560-1	\$21.41	\$3.40
Albuterol Aerosol Refill	17 g	1560-2	\$19.79	\$3.40

(WAR0000532) (Highly Confidential). Thus, Warrick touted a 529% spread on its albuterol inhalation aerosol and a 482% spread on the refill.

484. In a report to Congress, the GAO reported that albuterol sulfate was one of a small number of products that accounted for the majority of Medicare spending and volume. Albuterol sulfate accounted for 6.3% of total Medicare spending, ranking fifth out of more than 400 covered drugs. Albuterol sulfate ranked first for volume of units covered, accounting for 65.8% of total units reimbursed. *See* GAO Report to Congressional Committees, "Payments for

Covered Outpatient Drugs Exceed Providers' Cost," Tables 1 and 2, pp. 7-8 (GAO-01-0118 (P005546-005578)). The Schering Plough Group is one of three companies noted by the DOJ as manufacturing albuterol. *See* DHHS report, AB-00-86 (P006299-006316).

485. According to The Schering Plough Group's own documents, the published AWPs for most of its drugs were higher than the actual prices provided to wholesalers.

486. In response to government subpoenas, The Schering Plough Group produced numerous price lists setting forth spreads between AWPs and prices apparently offered to wholesalers, providers and other intermediaries. A review of those price lists reveals that Warrick has consistently offered hundreds of its drugs and other solutions to its customers at prices significantly below the published AWP and that the spread was of great importance to its customers. To repeat every one of those drugs and the spread offered to each specific customer here is not practical. However, set forth below in Tables 1, 2 and 3 are a number of those drugs with spreads between the AWPs and direct prices. Table 1 is an analysis of certain dosages of Warrick drugs from a document entitled, "Amerisource" (WAR0022160) (Highly Confidential).

TABLE 1

LABEL (MFG)	GENERIC NAME	AWP	INVOICE COST	DIFFERENCE	PERCENTAGE SPREAD
Warrick	Albuterol Inhaler	21.41	5.75	15.66	272%
	Aug Beta Dip Oint 0.05%	43.20	26.90	16.30	61%
	Griseofulvin	82.47	37.22	45.25	122%
	Theophylline	11.70	2.83	8.87	313%

Table 2 is an analysis of certain dosages of Warrick drugs from a document entitled, "1997 Care Group Bid Proposal." (WAR0022122) (Highly Confidential).

TABLE 2

PRODUCT	AWP	INVOICE PRICE	NET PRICE (AFTER REBATE)	DIFFERENCE BETWEEN AWP AND INVOICE PRICE	PERCENTAGE SPREAD
Clotrimazole	22.25	7.77	6.99	14.48	186%
Perphenazine	78.00	19.53	17.58	58.47	299%

Table 3 is an analysis of certain dosages of Warrick drugs from a document entitled, "Managed Care Pricing," dated July 1, 2002. (WAR0054226) (Highly Confidential).

TABLE 3

Product	Minimum PBM/Mail Order/ Staff Price Guide	Target PBM/Mail Order/ Staff Price Guide	Minimum GPO Price Guide	Target GPO Price Guide	AWP	Difference	% Spread
ISMN	4.48	4.93	5.15	5.38	117.40	112.02	2,082%
Oxaprozin	11.42	12.56	13.13	13.70	117.40	103.70	757%
Potassium Chloride	9.67	10.64	11.12	11.60	65.00	53.40	460%
Sodium Chloride	6.12	6.73	7.04	7.34	24.30	16.96	231%
Sulcrafate Tablets	45.15	49.67	51.92	54.18	353.71	299.53	553%

3. The DOJ Specifically Documented AWP Inflation for Albuterol Sulfate

487. In a report published by the DHHS (AB-00-86 (P006299-006316)), the DOJ documented at least one instance where the published AWPs for various dosages of albuterol sulfate manufactured by The Schering Plough Group were substantially higher than the actual prices listed by wholesalers. The following figures compare the DOJ's determination of an accurate AWP for one particular dosage, based upon wholesalers' price lists, with the AWP reported by The Schering Plough Group in the 2001 *Red Book*: The Schering-Plough Group reported to *Red Book* an AWP of \$30.25 for albuterol sulfate, yet the DOJ determined the actual AWP to be \$9.16, or \$21.09 less.

488. As stated in a May 4, 2000, letter from U.S. Rep. Tom Bliley, Chairman of the Congressional Committee on Commerce, to Raman Kapur, President of Warrick:

I am writing to you because one of the drugs reflecting a significant variation between the AWP-based prices paid by Medicare and the prices generally charged to private sector purchasers is albuterol sulfate, a drug manufactured by Warrick Pharmaceuticals.

(P006938-006941).

489. In his May 4, 2000, letter, Bliley outlined The Schering Plough Group's scheme with respect to the prescription drug albuterol sulfate. The government's investigation uncovered a significant spread between the amount Medicare reimbursed for albuterol sulfate and the amount the Schering-Plough Group actually charged. U.S. Rep. Bliley stated:

The OIG [Office of the Inspector General] has determined that the Medicare-allowed amount for albuterol sulfate, a pharmaceutical product sold by your company, in the Fiscal Year 1996 was \$.42. The OIG further estimated that the actual wholesale price of this drug was \$.15 and the highest available wholesale price that the OIG was able to identify was \$.21.

Id.

4. The Schering Plough Group Provided Free Goods and Other Incentives

490. In addition to marketing the spread, The Schering Plough Group has utilized other impermissible inducements to stimulate sales of its drugs. These inducements were designed to result in a lower net cost to the provider while concealing the actual wholesale price beneath a high invoice price. By utilizing "off-invoice" inducements, The Schering Plough Group provided purchasers with substantial discounts meant to gain their patronage while maintaining the fiction of a higher wholesale price.

491. As set forth above, The Schering Plough Group's scheme to inflate its reported AWPs and market the resulting spread to increase the market share of its drugs and its use of other "off invoice" rebates and financial inducements to its customers has resulted in excessive overpayments by Plaintiffs and the Class.

T. The Sicor Group (Sicor, Gensia and Gensia Sicor)

492. The Sicor Group engages in an organization-wide and deliberate scheme to inflate AWPs. The Sicor Group has stated fraudulent AWPs for all or almost all of its drugs, including those set forth below. The specific drugs of The Sicor Group for which relief is sought in this case are set forth in Appendix A, and are identified below:

Manufacturer	Brand Name (if applicable)	Generic Name	Therapeutic Category/Usage
SICOR GROUP (Sicor, Gensia and Gensia-Sicor)		acyclovir sodium	Anti-Infective Agent Used in the treatment of herpes infections
		amikacin sulfate	Antibiotic Agent (Anti-Infective Agent) Used to treat respiratory tract, urinary tract, bone, skin and soft tissue infections
		amphotericin b	Antifungal Agent (Anti-Infective Agent) Used to help the body overcome serious fungus infections
		doxorubicin hydrochloride	Antineoplastic Used in the treatment of ovarian cancer and AIDS-related Kaposi's sarcoma
		etoposide	Mitotic Inhibitor (Antineoplastic) Used in the treatment of testicular neoplasm and small cell cancer of the lung
		leucovorin calcium	Antianemic Agent (Blood Modifier) Used in the treatment of anemia
		pentamidine isethionate	Anti-Infective Agent Used in the treatment of pneumonia
		tobramycin sulfate	Antibiotic Agent (Anti-Infective Agent) Used to treat severe infection

1. The Sicor Group Has Been the Target of Government Investigations

493. In connection with its scheme to inflate AWPs, The Sicor Group has been investigated by the Department of Justice, Department of Health and Human Services Office of Inspector General, the Texas Department of Health, and the California Attorney General.

1. The Sicor Group Controls the Published AWP for Its Products

494. The Sicor Group has controlled and set the AWPs for its pharmaceutical products through direct communications with industry compendia during the Class Period. For example, by letter dated February 21, 1994, Gensia advised MediSpan of the impending launch of its new product called "Etoposide" and stated: "I have also include [sic] some guidelines in this pack for establishing Gensia's AWPs for our Etoposide." (SICOR 00955) (Confidential). That same day, Gensia sent a second letter to MediSpan stating, in part:

The following represents the detailed information for this product
and the AWP that we would like MediSpan to use:

ETOPOSIDE INJECTION

<u>NDC #</u>	<u>PRODUCT DESC.</u>	<u>VIALSIZE</u>	<u>LIST PRICE</u>	<u>AWP</u>
0703-5643-01	20MG/ML (100MG)	5ML	\$105.16	\$131.30
0703-5646-01	20MG/ML (500MG)	25ML	\$483.74	\$638.76

(SICOR 00956).

495. Moreover, The Sicor Group has told its sales force to rely on the AWP information contained in the industry compendia when marketing to customers. For example, a memorandum dated April 6, 1994 to "Field Sales force" regarding "Average Wholesale Prices (AWP)" provides in pertinent part:

Attached is a copy of Medi-Span's March 31, 1994 printout of product and AWP information for Gensia Laboratories. Since this information comes directly from Medi-Span's computer file, you will find it to be more accurate than the information that your customers are using from their reference texts. You will note, that the AWP information (listed in pack quantity) is found in the third column from the right. Additionally, the two columns to the immediate left of the AWP column represent: WAC (Wholesalers Acquisition Cost) and DP (Direct Price).

(SICOR 00753) (Highly Confidential).

2. The Sicor Group's AWP Manipulation Benefited Providers at the Expense of the Class

496. The Sicor Group has engaged in an ongoing deliberate scheme to inflate AWPs. For example, by letter dated September 25, 2000 to the HCFA administrator, the Chairman of the Commerce Committee revealed that: "[I]n 1998, a health care provider could buy Gensia's Etoposide for \$14.00, while the AWP used to determine Medicare reimbursement was \$141.97." (P007015-P007490).

497. The Sicor Group's marketing strategies further demonstrate its fraudulent practices. In a marketing document prepared by Gensia and obtained by the government in its investigation, Gensia stated:

Concentrate field reps on the top 40 AIDS hospitals using a \$54.00 price in conjunction with a 10% free goods program to mask the final price. Provides the account with an effective price of \$48.60 per vial.

See letter dated September 28, 2000 from U.S. Rep. Pete Stark to Alan F. Holmer, President of the Pharmaceutical Research and Manufacturers of America. (P007512).

498. Certain handwritten notations appear on this same marketing document comparing the AWP with other prices used for the same drug:

FSS \$44.95

Whls \$71.00

Distr. \$51.50

AWP \$109.20

(P007532).

499. Similarly, a document entitled "Comparison of AWPs" based on the 1996 *Red Book* contains the following handwritten notation:

Rob, Joe,

Tim suggested sending this info to the reps. Your thoughts?

B

(SICOR 00756) (Highly Confidential). Following this notation is a chart comparing the AWPs for certain drugs published by various manufacturers, including Gensia. One example follows:

Doxurubicin		Abbott/ Adria	Bedford	FUSA	Gensia		
					X		
10		\$48.31	\$47.35	\$44.50	\$49.29	<Polymer	
					X		
50		\$241.56	\$236.74	\$231.00	\$246.46	<Polymer	
					X		
200		\$946.94	\$945.98	NA	\$966.14	<Polymer	

Id.

500. Moreover, Gensia disseminated advertisements that actually contained a comparison of the Contract Price with the AWP and set forth the resulting spread (SICOR 00751, 00752) (Highly Confidential), because Gensia knew that marketing the spread was in its

best interests. Realizing this, one customer of Gensia, Opti Care, sent a memorandum to all its offices (with a copy to Gensia) stating: "Gensia's products offer a significant spread between AWP and contract price. This spread may be attractive, when a payor's reimbursement is based on AWP and the drug is not MAC'd. (SICOR 00758) (Highly Confidential).

3. Specific Sicor Group AWPs Documented by the DOJ

501. In a report published by the DHHS, the DOJ documented at least 17 instances where the published AWPs for various dosages of drugs manufactured by The Sicor Group were substantially higher than the actual prices listed by wholesalers. The chart below sets forth the drugs identified by the DOJ and the spread associated with one particular dosage of each drug. These figures compare the DOJ's determination of an accurate AWP for that particular dosage, based upon wholesalers' price lists, with the AWP reported by The Sicor Group in the 2001 *Red Book*.

Drug	The Sicor Group's 2001 Red Book AWP	DOJ Determined Actual AWP	Difference	Spread
Acyclovir Sodium	\$125.00 ¹⁰	\$100.00	\$25.00	25%
Amikacin Sulfate	\$87.50	\$72.68	\$14.82	20%
Tobramycin Sulfate	\$342.19	\$6.98	\$335.21	4,802%

(P006299-006316).

4. Inflated Sicor Group AWPs From the Sicor Group's Price Lists

502. According to The Sicor Group's own documents, the published AWPs for its drugs were higher than the actual prices provided to wholesalers. In response to government subpoenas, The Sicor Group produced numerous price lists setting forth spreads between AWPs and prices apparently offered to wholesalers, providers and other intermediaries. A review of those price lists reveals that The Sicor Group has consistently offered hundreds of its drugs and

¹⁰ Calculation based on the AWP listed in the 2000 *Red Book*.

other solutions to its customers at prices significantly below the published AWP and that the spread was of great importance to its customers. To repeat every one of those drugs and the spread offered to each specific customer here is not practical. However, set forth below in Tables 1 and 2 are a number of those drugs with spreads between the AWPs and direct prices. Table 1 is an analysis of certain dosages of two Gensia drugs from a Medi-Span printout on which Gensia wanted its sales force to rely (the remaining drugs were redacted by The Sicor Group prior to production). (SICOR 00754-755) (Highly Confidential).

Table 1

Product	WAC	DP	AWP	DIFFERENCE (between AWP and DP)	PERCENTAGE SPREAD
Etoposide Inj	483.73	483.73	638.76	155.03	32%
Leucovorin CA Inj	32.50	32.50	40.63	8.13	25%

503. Table 2 is an analysis of certain dosages of four Gensia drugs from multiple Gensia price lists for a particular customer, Pharmaceutical Buyers, Inc., comparing the customer's Contract Price with the AWP and the resulting spread (the remaining drugs were redacted by The Sicor Group prior to production). (SICOR 00555, 573, 614, 633) (Highly Confidential).

Table 2

Product	AWP	PBI CONTRACT	SPREAD	PERCENTAGE SPREAD
DOXURUBICIN HYDROCHLORIDE	871.70	293.60	578.10	1,969%
ETOPOSIDE	1207.33	456.00	751.33	1,648%
LEUCOVORIN CALCIUM	39.00	4.58	34.42	752%
PENTAMIDINE ISETHIONATE	468.00	193.75	274.25	1,415%

5. The Sicor Group Provided Free Goods and Other Incentives

504. In addition to marketing the spread, The Sicor Group has utilized other impermissible inducements to stimulate sales of its drugs. These inducements were designed to result in a lower net cost to the provider while concealing the actual wholesale price beneath a high invoice price. By utilizing "off-invoice" inducements, such as free goods, The Sicor Group

provided purchasers with substantial discounts meant to gain their patronage while maintaining the fiction of a higher wholesale price. (SICOR 00718, 04182, 00689) (Highly Confidential).

505. As set forth above, The Sicor Group's scheme to inflate its reported AWPs and market the resulting spread to increase the market share of its drugs and its use of other "off invoice" rebates and financial inducements to its customers has resulted in excessive overpayments by Plaintiffs and the Class.

U. TAP

506. TAP engages in an organization-wide and deliberate scheme to inflate AWPs. TAP has stated fraudulent AWPs for Prevacid, as set forth in Appendix A, and identified below:

Manufacturer	Brand Name (if applicable)	Generic Name	Therapeutic Category/Usage
TAP	Prevacid	lansoprazole	Proton Pump Inhibitor (Gastrointestinal Agent) Used in the short-term treatment of duodenal ulcer, erosive esophagitis and gastroesophageal reflux disease

1. TAP Has Been the Target of Government Investigations

507. In connection with its scheme to inflate AWPs, TAP has been investigated by the Department of Justice.

508. On October 13, 2001, the United States Attorney in Boston, Massachusetts announced that TAP had agreed to pay \$875 million to resolve criminal charges and civil liabilities in connection with its fraudulent pricing and marketing practices for the drug named Lupron®. As part of the agreement:

a TAP agreed to plead guilty to a conspiracy to violate the Prescription Drug Marketing Act, 21 U.S.C. §§ 331(t) and 333(b), and to pay a \$290 million criminal fine, the largest criminal fine ever in a health care fraud prosecution. The plea agreement between the United States and TAP specifically stated that TAP's criminal conduct caused the Government losses of \$145,000,000;

b. TAP agreed to pay the United States Government \$559,483,560 for filing false and fraudulent claims with the Medicare and Medicaid programs as a result of TAP's fraudulent drug pricing schemes and sales and marketing misconduct;

c. TAP agreed to pay the fifty states and the District of Columbia \$25,516,440 for filing false and fraudulent claims with the States, as a result of TAP's drug pricing and marketing misconduct, and for TAP's failure to provide state Medicaid programs TAP's best price for Lupron®, as required by law;

d. TAP agreed to comply with the terms of a sweeping Corporate Integrity Agreement that, among other things, significantly changes the manner in which TAP supervises its marketing and sales staff and ensures that TAP will report to the Medicare and Medicaid programs the true average sale price for drugs reimbursed by those programs;

e. Abbott and Takeda agreed to cooperate fully with the ongoing government investigation of TAP and its former officers and employees in exchange for the United States declining prosecution of Abbott and Takeda for conduct relating to Lupron®; and

f. An Indictment was unsealed in the District of Massachusetts against six current or former TAP employees (including an account executive, three District Managers, a National Accounts Manager and the former Vice President of Sales), and a urologist, alleging that they conspired to (i) bill Medicare for free samples of Lupron® and (ii) market Lupron® using the "spread" and the "return to practice" program.

The TAP defendants have been sued in a separate class action in connection with their fraudulent pricing and marketing practices for Lupron®.

509. At a hearing in the criminal matter, which has an extensive record, United States District Court Judge William G. Young found:

This has been a gross abuse of the Medicare/Medicaid repayment system, knowing, intelligent. You have demonstrated, and it's all

been confirmed in open court, and I don't want anyone forgetting about the fact that this company, not under its present management, knowingly abused the public trust in a most, and I use my words carefully, despicable way.

United States v. TAP Pharm. Prods., Inc., No. CR-01-10354-WGY (D. Mass. Dec. 6, 2001).

1. TAP Controls the Published AWP for Its Products

510. TAP has controlled and set the AWPs for its pharmaceutical products through direct communications with industry compendia during the Class Period.

2. TAP's AWP Manipulation Benefited Providers at the Expense of the Class

511. According to Criminal Information filed against several doctors and the Indictment filed against six former TAP employees and a urologist, TAP referred its practice of inflating the AWP for Lupron and the corresponding inducement to the physicians as its "Return to Practice" program.

512. At various times, TAP employees would conduct a "Business Review Meeting" with individual doctors or their staff to explain in detail how a doctor could make money by buying Lupron® and exploiting the spread.

513. TAP created sophisticated computer programs, including spreadsheets for use with physicians, to further explain how "Return to Practice" worked and how much money a physician could make from the spread. These computer programs were loaded onto laptop computers used by sales representatives and taken directly into physician's offices.

514. TAP knew and understood that, because Medicare and other insurers relied upon the Publishers to establish AWPs, and because TAP could precisely control the published AWP, TAP could increase whenever they so desired the profit obtained by physicians from Plaintiffs and the Class.

3. TAP Provided Free Goods and Other Incentives

515. In addition to marketing the spread, Watson has utilized other impermissible inducements to stimulate sales of its drugs. These inducements were designed to result in a

lower net cost to the provider while concealing the actual wholesale price beneath a high invoice price.

516. For example, TAP has pled guilty to illegally conspiring with medical providers to provide free samples which would then be billed to Medicare. In an October 3, 2001, press release that referenced the guilty plea, TAP's president, Thomas Watkins, stated:

We admit that TAP provided free samples of Lupron to a number of physicians, primarily in the early to mid-1990s, with the knowledge that those physicians would seek and receive reimbursement. The billing for free samples is wrong, and it should never have happened.

517. TAP has also provided and/or arranged for many other non-public financial inducements to stimulate the sales of its drugs at the expense of Plaintiffs and the Class. Such inducements included volume discounts, rebates, off-invoice pricing, free goods, credit memos, consulting fees, debt forgiveness and grants. All of these incentives are designed to lower the cost of the drug to the medical provider while concealing the actual cost from Plaintiffs and the Class.

518. For example, the Indictment alleges three specific instances when TAP employees offered an HMO, a urology practice and a hospital unrestricted "educational grants" of more than \$75,000 to continue their use of Lupron. It offered Tufts HMO \$65,000 in grants.

519. Another way that TAP funneled illicit payments to physicians was through the "TAP into the Future" program, which consisted of providing physicians with all-expense paid weekends at luxurious resorts. These junkets were disguised as educational or consulting programs, with all of the doctors in attendance designated as "consultants" even though the doctors who attended did not do anything that could reasonably be deemed consulting services.

520. As set forth above, TAP scheme to inflate its reported AWPs and market the resulting spread to increase the market share of its drugs and its use of other "off invoice" rebates

and financial inducements to its customers has resulted in excessive overpayments by Plaintiffs and the Class.

4. TAP Concealed Its AWP Manipulation

521. TAP deliberately acted to conceal its fraudulent reporting and marketing of the AWP spread.

522. For example, TAP instructed physicians not to report the true price they paid for Lupron. According to the Indictment, a TAP Senior Marketing executive, Alan MacKenzie, advised TAP's sales force to:

tell physicians that if doctors disclosed their invoice costs to the Medicare Program, that Program would take steps to reduce the maximum payment allowed for Lupron and thus reduce the physician's profit for Return to Practice.

523. MacKenzie also told the sales force to caution doctors not to discuss their price discounts with other physicians and instructed TAP employees to tell urologists that:

by discussing your costs of Lupron with other physicians, you run the risk of that information getting back to HCFA. If HCFA then realizes that AWP is not a true reflection of the price, the AWP could be affected, thus lowering the amounts you may charge.

524. A presentation to TAP's sales representatives included the same statements listed above, as well as directions for the leader of the presentation, which stated:

The main point to make to physicians is that confidentiality clause is a protection for them. If word is leaked back to HCF/Medicare that the cost of Lupron is going down, they very well may take steps in reducing allowable. This tactic should help prevent physicians talking amongst themselves.

V. Warrick

525. Warrick has acted to inflate AWPs pursuant to the scheme identified above. The specific drugs are identified in Appendix A.

W. Watson

526. Watson engages in an organization-wide and deliberate scheme to inflate AWPs.

Watson has stated fraudulent AWPs for all or almost all of its drugs, including: Ferrlecit, Verapamil HCL, Vinblastine Sulfate, Vincristine Sulfate, Dexamethasone, Diazepam, Gentamicin, Testosterone Ethanate, Vancomycin, Fluphenazine, Gemfibrozil, Imipramine, Nadolol, and Perphenazine. The specific drugs of Watson for which relief is sought in this case are set forth in Appendix A, and as identified below:

Manufacturer	Brand Name (if applicable)	Generic Name	Therapeutic Category/Usage
WATSON (Watson and Schein)	Ferrlecit	sodium ferric gluconate complex in sucrose injection	Iron Preparation (Blood modifier) Used for treatment of anemia in patients undergoing hemodialysis
	InfeD	iron dextran	Iron Preparation (Blood modifier); Nutritional Supplement Used for treatment of iron deficiency
		dexamethasone acetate	Hormone; Glucocorticoid Used to treat inflammatory conditions, hematologic disorders and cerebral edema
		dexamethasone sodium phosphate	Hormone; Glucocorticoid Used to treat inflammatory conditions, hematologic disorders and cerebral edema
		diazepam	Central Nervous System Agent Used to treat status epilepticus and anxiety disorders. Also used as an amnesic prior to surgical procedures
		estradiol	Estrogen (Hormone) Used for treatment of menopausal symptoms and postmenopausal osteoporosis
		fluphenazine hcl	Central Nervous System Agent; Psychotherapeutic Agent Used to manage psychotic disorders
		gemfibrozil	Antilipemic Agent (Cardiovascular Agent) Used to lower cholesterol
		gentamicin sulfate	Anti-Infective Agent Used as a general antibiotic to treat serious gastrointestinal, respiratory, bone, skin and soft tissue infections
		imipramine hcl	Central Nervous System Agent; Psychotherapeutic Agent Used in the treatment of depression

Manufacturer	Brand Name (if applicable)	Generic Name	Therapeutic Category/Usage
		lorazepam	Central Nervous System Agent Used for treatment of anxiety disorders
		nadolol	Antihypertensive (Cardiovascular Agent) Used in the treatment of hypertension and management of angina
		perphenazine	Central Nervous System Agent; Psychotherapeutic Agent Used to manage psychotic disorders
		propanolol hcl	Beta Adrenergic Blocking Agent (Cardiovascular Agent) Used to treat hypertension
		ranitidine hcl	Histamine Receptor Antagonist (Gastrointestinal Agent) Used for treatment of duodenal ulcer, gastric ulcer, gastroesophagael disease and heartburn
		vancomycin hcl	Antibiotic Agent (Anti-Infective Agent) Used as a general antibiotic
		verapamil hcl	Calcium Channel Blocker (Cardiovascular Agent) Used in the treatment of tachyarrhythmia, angina and hypertension

1. Watson Has Been the Target of Government Investigations

527. In connection with its scheme to inflate AWPs, Watson has been investigated by the Department of Justice, Department of Health and Human Services Office of Inspector General, and the State of California.

1. Watson's Definition and Understanding of AWP

528. Watson plainly recognizes that "AWP drives reimbursement." (MDLW12564) (Highly Confidential).

2. Watson Controls the Published AWP for Its Products

529. Watson has controlled and set the AWPs for its pharmaceutical products through direct communications with industry compendia during the Class Period. In a memo, Watson states that it is faxing prices to various pricing services, but "not all pricing services received all of the prices listed on this letter. Most only received the AWP price..." The memo goes on to

state that “AWP is the primary price being communicated in these faxes to establish a reference for reimbursement.” (MDLW25203) (Highly Confidential).

530. A *Red Book* Product Listing Verification form asks for approval of changes to the stated AWP for Schein’s (which was later acquired by Watson) Verapamil HCL, Vinblastine Sulfate and Vincristine Sulfate. A Schein executive okayed the changes and signed the *Red Book* form. (MDLW00887).

3. Watson’s AWP Manipulation Benefited Providers at the Expense of the Class

531. When deciding where to set the price for its drug Ferrlecit, Watson recognized that, in a Medicare Reimbursement Mechanism, “margin drives AWP and ASP” and that a goal of setting the price is that “profit margin at the unit level must not decrease.” Watson recognizes that 20% of reimbursement is patient co-pay, which can be private insurance, Medicaid or cash. (MDLW05457-05460) (Highly Confidential).

532. Watson was well aware that payors relied on the AWP, and was sensitive to avoid alerting payors to Watson’s AWP manipulation. In the context of a pricing study, a Schein executive noted that “it would be great to get a read from some HCFA personnel regarding what level of price will set off alarms with reimbursement.” (MDLW25216) (Highly Confidential).

533. In that same document, Watson acknowledges that AWP manipulation is the key to its customers’ profits “if through reimbursement we can maintain or increase the money a unit makes on using this product does the price even matter?” (MDLW25216) (Highly Confidential).

4. Specific Watson AWPs Documented by the DOJ

534. In a report published by the DHHS (AB-00-86), the DOJ documented at least 12 instances where the published AWPs for various dosages drugs manufactured by Watson were substantially higher than the actual prices listed by wholesalers. The chart below sets forth the drugs identified by the DOJ and the spread associated with one particular dosage of each drug.

These figures compare the DOJ's determination of an accurate AWP for that particular dosage, based upon wholesalers' price lists, with the AWP reported by Watson in the *Red Book*.

Drug	Watson's 1998-2001 Red Book AWPs	DOJ Determined Actual AWP	Difference	Spread
Dexamethasone Acetate	\$46.45 (1998)	\$11.50	\$34.95	304%
Dexamethasone Sodium Phosphate	\$93.04 (2001)	\$1.08	\$91.96	851%
Diazepam	\$18.15 (2000)	\$2.50	\$15.65	626%
Gentamicin Sulfate	\$114.10 (1999)	\$1.18	\$112.92	957%
Iron Dextran	\$377.04 (2001)	\$24.69	\$352.35	1,427%
Testosterone Ethanate	\$42.10 (2001)	\$13.39	\$28.71	214%
Vancomycin HCL	\$70.00 (1998)	\$3.84	\$60.16	1,567%

(P006299-P006316).

5. Inflated Watson AWPs From Watson's Price Lists

535. In response to government subpoenas, Watson produced numerous price lists setting forth spreads between AWP and prices offered to wholesalers, providers and other intermediaries. A review of those lists indicates that Watson has consistently offered drugs to its customers at prices significantly below the published AWP, and that the spread was of great importance to Watson's customers. It is not practical to repeat every one of those drugs and the spread offered to specific customers. However, set forth below in Table 1 are a number of those drugs (not already referenced above) and the substantial spread offered to Watson customers.

536. Table 1 is an analysis of certain dosages of Schein drugs from a chart titled Schein Product Status Report, February 1996. (MDLW01237).

Table 1

Drug	AWP	WAC	% Spread
Fluphenazine HCL 1mg	\$46.08	\$15.71	193%
Gemfibrozil 600mg	\$55.65	\$7.95	600%
Imipramine HCL 10mg	\$4.45	\$1.32	237%
Nadolol 20mg	\$85.32	\$42.95	98%
Perphenazine 2mg	\$42.53	\$19.76	115%

537. As set forth above, Watson's scheme to inflate its reported AWPs and market the resulting spread to increase the market share of its drugs has resulted in excessive overpayments by Plaintiffs and the Class.

6. Watson Provided Free Goods and Other Incentives

538. In addition to marketing the spread, Watson has utilized other inducements to stimulate sales of its drugs. These inducements were designed to result in a lower net cost to the provider while concealing the actual wholesale price beneath a high invoice price. In one instance in May 2000, Schein offered "Priority Customers" an additional 5% discount on Ferrlecit "off invoice" for all purchases made that month. (MDLW15896.) By utilizing "off-invoice" inducements, Watson provided purchasers with substantial discounts meant to gain their patronage while maintaining the fiction of a higher wholesale price.

539. As set forth above, Watson's scheme to inflate its reported AWPs and market the resulting spread to increase the market share of its drugs and its use of other "off invoice" rebates and financial inducements to its customers has resulted in excessive overpayments by Plaintiffs and the Class.

7. Watson Concealed Its AWP Manipulation

540. Watson deliberately acted to conceal its fraudulent reporting and marketing of the AWP spread. For example, as noted above, Watson reported its AWP to various industry compendia, but disclosed WAC, direct price and average sale price to only a very few, if any, outside entities. (MDLW25204) (Highly Confidential). Also as noted above, Watson needed to keep the AWP high, but at a level that would not "set off alarms with reimbursement" (MDLW25216). Watson effectively hid the AWP spread from Plaintiffs and the Class.

VI. DIRECT DAMAGE SUSTAINED BY PLAINTIFFS AND THE MEMBERS OF THE AWP CLASS

541. Plaintiffs and other Third-Party Payors who are members of the class reimburse health care providers for pharmaceuticals based upon the published AWP for brand name drugs

and based upon MAC, for generic drugs, which in turn is derived from AWP. Accordingly, plaintiffs and Third-Party Payors are directly damaged by fraudulent AWP pricing schemes for drugs covered by employee health and benefit plans. By virtue of the fact that AWP is the reimbursement benchmark for pricing of the AWPs at issue, such injury occurs in all aspects of the distribution chain for the AWPs, including the PBM segment, non-PBM purchases, Part B covered drugs and non-Part B covered drugs.

VII. CERTAIN DEFENDANTS USE AWP TO ENGAGE IN A SCHEME TO FIX PRICES – THE TOGETHER CARD SCHEME

A. The Formation of the Together Card Conspiracy

542. Beginning in 2001 or 2002, the exact date of which is not yet known but is discoverable, certain of the Defendants also began to use AWPs and the growing concern over the cost of care to seniors, for another purpose – to artificially fix and/or increase the spread between their posted AWPs and their posted wholesale acquisition cost, or WAC, in connection with the commencement of the Together Card Program.

543. Defendants Abbott, AstraZeneca, Aventis, BMS, GSK, Novartis and J&J, through its subsidiaries Janssen and Ortho-McNeil (“the Founding Together Card Defendants”), later Defendant TAP, and an alliance they formed, Defendant Together Rx LLC (the “Together Card Defendants”), have engaged in a conspiracy to fix the AWP spread of drug prices in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1, 18 U.S.C. § 1962(c), and certain state antitrust laws.

544. This conspiracy was accomplished with the use of the Together Rx Card Program (“Together Card Program”), which was supposedly designed as a prescription drug savings program for older, uninsured and poor Americans. The Together Card Defendants, in conjunction with their establishment and ongoing management of the Together Card Program, have agreed and conspired among themselves to raise, fix, maintain and/or stabilize the AWP

spread of over 170 widely prescribed brand name drugs (the “Together Card Drugs”) purchased through, and outside of, the Together Card Program.

545. The Together Card Defendants’ agreement and conspiracy have caused Plaintiffs and the Nationwide End Payor Together Card Class during the class period to pay more for the Together Card Drugs than they would have if the Together Card Defendants had not engaged in their unlawful practices. Plaintiffs and the Nationwide End Payor Together Card Class have therefore been damaged due to the Together Card Defendants’ conspiracy to raise, fix, maintain and/or stabilize the AWP spread of the Together Card Drugs.

546. Defendant Together Rx LLC, a Delaware limited liability company, was formed by the Founding Together Card Defendants as an alliance to effectuate this conspiracy. Indeed, these Founding Together Card Defendants refer to themselves as the “Founding Partners” of the alliance and the Together Card Program. The alliance and Together Card Program facilitated the sharing of price information, and the information and maintenance of the Together Card Defendants’ conspiracy.

B. The Drug Discount Card Response to the Lack of Medicare Drug Coverage and the Underpinnings of the Together Card Scheme

547. In 2001, Americans spent over \$172 billion on prescription drugs. The total is expected to more than double in a few years. Elderly Americans bear a disproportionate burden. While accounting for only 13 percent of the U.S. population, seniors pay for more than one-third of all prescription drugs. The average senior spent \$1,756 for prescription drugs in 2001, with nearly half of that (\$858) coming out of pocket.

548. Congress has long debated whether to add a prescription drug benefit to the Medicare program. Currently, however, the Medicare Program generally does not cover the cost of self-administered prescription drugs. Accordingly, it is estimated that nearly one-third of the 40 million Medicare beneficiaries in the U.S. have no prescription drug coverage.

549. Recently, Congress began considering a number of other measures designed to lower the cost of prescription drugs for U.S. seniors, including price controls and the importing of cheaper drugs from countries with price controls. For example, on April 4, 2001, U.S. Rep. Tom Allen (D-Maine) reintroduced the Prescription Drug Fairness for Seniors Act to protect senior citizens from drug price discrimination and make prescription drugs available to Medicare beneficiaries at substantially reduced prices. According to Rep. Allen, the legislation is intended to allow pharmacies that serve Medicare beneficiaries to purchase prescription drugs at the average price that the drugs are sold in other developed nations. Rep. Allen estimated that his legislation would reduce prices for brand name prescription drugs, on average, by 40 percent.

550. Faced with growing Congressional and public scrutiny, and recognizing that true drug pricing reform would likely involve price controls or other unwelcome government regulation, certain Defendants introduced a number of pharmaceutical “discount” cards to Medicare beneficiaries.

1. GSK Orange Card

551. On October 3, 2001, GSK launched its Orange Card. According to a GSK press release, the Orange Card – an innovative prescription medicine savings program for seniors in need – was created to “help address a critical gap in prescription drug coverage.” The Orange Card, an extension of GSK’s patient assistance program, was purportedly designed so participants “will realize average savings of 30% off the usual price they pay for all outpatient GSK medicines. In some cases, savings may be 40% or greater.” The Orange Card, effective January 1, 2002, is completely free to participants.

552. GSK claimed that Orange Card participants would receive direct savings on their purchase of GSK outpatient prescription drugs equal to 25% of its list price to wholesalers – AWP – as reported by *First DataBank*. GSK indicated that participating pharmacies will charge Orange Card holders no more than a negotiated price for outpatient GSK prescription drugs.

Because of variations in pharmacy prices, according to GSK, actual savings to Orange Card participants on each prescription will vary. However, GSK expected participants to realize average savings of 30% off the price individuals without prescription drug coverage would usually pay for GSK medicines at their pharmacy. In some cases, GSK claimed that savings could be 40% or greater depending on their pharmacy's usual and customary price for the prescribed GSK medicine.

553. The same press release quoted GSK CEO Jean-Pierre Garnier:

The GlaxoSmithKline Orange Card program assists low-income seniors who have no prescription coverage. We support a Medicare prescription drug benefit, but while the issue is still being debated in Congress, GSK wants to provide relief now for America's most needy seniors.

We spend a great deal of time and effort in developing effective medicines. With the Orange Card, we hope to help participants be able to afford to follow their doctors' prescribed treatment and realize the full value of those medicines through a longer healthier life.

554. According to the October 3, 2002 press release, eleven million seniors are eligible for the Orange Card. Those eligible are senior citizens age 65 and older, and the disabled, who are enrolled in Medicare and: (1) have annual incomes at or below 300% of the federal poverty level (annual incomes at or below \$26,000 single or \$35,000 for a couple) and (2) lack public or private insurance programs or other pharmaceutical benefit programs, such as Medicaid.

555. GSK reported that seniors and other Medicare beneficiaries could apply for the Orange Card through healthcare providers or by calling a toll-free number. The Orange Card application process began immediately, and participants could begin using it on January 1, 2002. According to GSK, seniors could simply present the Orange Card with their prescription to their pharmacist to receive the savings on GSK outpatient prescriptions. GSK retained Express Scripts Specialty Distribution Services to administer the Orange Card program.

556. By October 2002, just one year after the launch of the Orange Card, GSK had enrolled over 100,000 seniors and other Medicare beneficiaries. GSK's participation in the Together Card alliance did not affect its Orange Card program. Orange Card and Together Card participants receive identical discounts on all GSK outpatient prescriptions.

1. Novartis Care Card

557. In November of 2001, just one month after GSK announced the Orange Card, Novartis launched its Care Plan. Novartis claims that the Novartis Care Plan "is a comprehensive and flexible prescription savings plan that offers help to a broad range of lower income patients enrolled in Medicare without prescription drug coverage." The Care Plan, effective January 1, 2002, purports to be completely free to participants.

558. The Care Plan claims to offer "participating prescription medicines to patients with annual income up to \$18,000 (\$24,000 per couple) for a \$12 flat fee per prescription. Individuals whose annual income is between \$18,000-28,000 (\$24,000-38,000 per couple) will receive 25-40% savings off their usual [AWP] price, on selected Novartis products." Novartis estimated that eleven million Medicare recipients might be eligible for its Care Plan.

559. According to Novartis, eligible applicants would receive a Care Card from either Novartis or their participating pharmacy. Participants would present their Care Card and prescription to a participating pharmacy. The pharmacist would automatically reduce the participant's cost based on his or her eligibility. In turn, Novartis paid participating pharmacies \$5 per enrollee. Novartis retained McKesson Health Solutions to administer its Care Card.

560. Although existing cardholders could still use the Novartis Care Card, after the launch of the Together Card in April of 2002, Novartis directed all of its new Care Plan applicants to the Together Card.

561. Novartis, on its company website, offered an explanation as to why it forged an alliance with six competing pharmaceutical manufacturers:

When the Novartis Care Card was launched, *Novartis issued a call-to-action asking other pharmaceutical companies to help create an interim solution to help Medicare recipients who lack drug coverage.* Novartis joined the Together Rx card to help this population gain access to medicines with a single, easy-to-use card. The Together Rx card represents a voluntary industry contribution to an immediate interim solution for millions of Medicare enrollees without prescription drug coverage. Each of the participating companies supports long-term solutions by federal and/or state governments. [Emphasis added.]

C. Implementation of the Together Rx Card Program

562. On April 10, 2002, the Together Card Defendants announced their new pharmaceutical alliance, Defendant Together Rx, LLC. According to the Together Card Defendants' joint press release:

For the first time, millions of people enrolled in Medicare will have access to savings on more than 150 widely prescribed medicines through one free, easy-to-use card unveiled by seven major pharmaceutical companies. By offering one-card access to savings on more medicines than any existing pharmaceutical company savings program, the Together Rx Card makes it easier for 8 to 11 million Medicare enrollees who have no prescription drug coverage to get the medicines they need to help them maintain active and independent lifestyles.

The lack of prescription drug coverage among Medicare beneficiaries is a serious national problem that no individual company can solve.

Together Rx encourages other pharmaceutical companies to join the coalition in this significant step forward.

563. BMS states on its website that it "has teamed up" with the other Together Card Defendants to form the Together Card Program, which BMS describes as "the most comprehensive savings program ever offered by the pharmaceutical industry." It further states: "One free card + seven pharmaceutical companies = significant savings."

564. The alliance of Together Card Defendants states that it has communicated with "about a dozen manufacturers" to join the alliance. The Chief Executive Officer of at least one

major pharmaceutical company that created its own discount card program publicly rejected a joint discount program among competing pharmaceutical companies because it violated “antitrust regulations.” See Niala Boodhoo, “Lilly Joins Discount Drug Card Bandwagon,” *Reuters*, Mar. 12, 2002.

565. Although not a Founding Together Card Defendant, TAP’s website presently indicates that it participates in the Together Card Program through its blockbuster drug, Prevacid (along with Abbott). Prevacid’s U.S. sales in 2002 totaled \$3.7 billion.

566. The Together Card Defendants claim that the Together Card Program, effective in early June of 2002, provides savings to eligible Medicare enrollees on more than 170 widely prescribed brand name medicines, including 26 different medicines used to treat diabetes, hypertension, high cholesterol, cancer, allergy, asthma, arthritis and depression, which are among the most common conditions affecting older Americans.

567. The Together Card Defendants prominently proclaim that members will “save on these brand-name medicines with Together Rx.” The medicines are: Accolate, Aciphex, Advair Diskus, Agenerase, Albenza, Allegra, Allegra-D Extended Release Tablets, Amaryl, Amerge, Amoxil, Anxemet Tablets, Arava Tablets, Arimidex, Atacand, Atacand HCT, Augmentin, Avandamet, Avandia, Avodart, Axert, Azmacort Inhalation Aerosol, Bactroban Cream, Beconase, Biaxin Filmtab, Biaxin XL Filmtab, Biaxin Granules, Bicitra, BuSpar, Carafate Tablets and Suspension, Casodex, Ceftin Tablets and Power for Oral Suspension, Cefzil, Clozaril, CombiPatch, Combivir, Compazine, Comtan, Concerta, Coreg, Coumadin, Daraprim Tablets, Depakote, Depakote Sprinkle Capsules, Depakote ER, Dexedrine, DiaBeta, Diovan, Diovan HCT, Ditropan, Duragesic, Dyazide, Elidel, Elmiron, Emla Anesthetic Disc, Emla Cream, Entocort EC, Epivir, Epivir-HBV, Erycette, Eskalith CR, Estraderm, Exelon, Famvir, Femara, Flexeril, Flonase, Flovent, Floxin, Focalin, Glucophage, Glucophage XR, Glucovance, Grifulviin V, Imitrex, Kaletra, Lamictal, Lamisil, Lanoxicaps, Lanoxin, Lantus, Lasix,

Lescol/Lescol XL, Leukeran Tablets, Levaquin, Lotensin, Lotensin HCT, Lotrel, Malarone, Mavik, Mepron, Metaglip, Miacalcin Injection & Nasal Spray, Monistat-Derm, Monopril, Monopril-HCT, Mycelex, Myleran, Nasacort, Nasacort AQ Nasal Spray, Neutraphos, Nexium, Nolvadex, Norvir, Omnicef Capsules/Oral Suspension, Pancrease, Parafon Forte DSC, Parlodel, Parnate, Paxil, Plendil, Polycitra, Pravachol, Prevacid, PrevPac, Prilosec, Pulmicort Turbuhaler, Purinethol, Regranex, Relafen, Relenza, Reminyl, Renova, Requip, Rescula, Retin-A, Retrovir, Rhinocort Aqua Nasal Spray, Risperdal, Risperdal M-Tab, Ritalin hydrochloride, Ritalin LA, Serevent, Seroquel, Serzone, Sinemet, Sinemet CR, Spectazole, Sporanox, Starlix, Stelazine, Synthroid, Tabloid brand Thiguanine, Tagamet, Tarka, Tegretol, Tegretol XR, Tequin, Terazol, Thorazine, Tolectin, Topamax, Toprol-XL, Trental, TriCor, Trileptal, Trizivir, Tylenol with Codeine, Tylox, Ultracet, Ultram, Urispas, Valtrex, Vascor, Ventolin, Vermos, Vivelle/Vivelle-Dot, Voltaren Ophthalmic, Wellbutrin SR, Zaditor, Zantac, Zelnorm, Ziagen, Zofran, Zomig, Zomig-ZMT, Zovirax, and Zyban.

568. The drugs manufactured by Abbott and distributed through the Together Card Program, include but may not be limited to: Biaxin Filmtab, Biaxin XL Filmtab, Depakote, Depakote Sprinkle Capsules, Depakote ER, Kaletra, Mavik, Norvir, Omnicef Capsules/Oral Suspension, Prevacid, PrevPac, Synthroid, Tarka, and TriCor.

569. The drugs manufactured by AstraZeneca and distributed through the Together Card Program include, but may not be limited to: Accolate, Arimidex, Atacand, Atacand HCT, Casodex, Emla Anesthetic Disc, Emla Cream, Entocort, Nexium, Nolvadex, Plendil, Prilosec, Pulmicort Turbuhaler, Rhinocort Aqua, Seroquel, Toprol, Zomig, and Zomig-ZMT.

570. The drugs manufactured by Aventis and distributed through the Together Card Program include, but may not be limited to: Allegra, Allegra-D, Amaryl, Anzemet Tablets, Arava Tablets, Azmacort, Carafate Tablets and Suspension, DiaBeta, Intal, Lantus, Lasix, Nasacort, Nasacort AQ, Tilade, and Trental.

571. The drugs manufactured by BMS and distributed through the Together Card Program include, but may not be limited to: BuSpar, Cefzil, Coumadin, Glucophage, Glucophage XR, Glucovance, Metaglip, Monopril, Monopril HCT, Pravachol, Serzone, Sinemet, Sinemet CR, and Tequin.

572. The drugs manufactured by GSK and distributed through the Together Card Program include, but may not be limited to: Agenerase, Albenza, Alkeran Tablets, Amerge, Amoxil, Augmentin, Avandamet, Avandia, Avodart, Bactroban Cream, Beconase, Ceftin Tablets and Powder for Oral Suspension, Combivir, Compazine, Coreg, Daraprim Tablets, Dyazide, Epivir, Epivir-HBV, Eskalith CR, Flonase, Flovent, Imitrex, Lamictal, Lanoxicaps, Lanoxin, Leukeran Tablets, Malarone, Mepron, Myleran, Parnate, Paxil, Purinethol, Relafen, Relenza, Requip, Retrovir, Serevent, Stelazine, Tagamet, Tabloid brand Thioguanine, Thorazine, Trizivir, Urispas, Valtrex, Ventolin, Wellbutrin, Zantac, Ziagen, Zofian, Zovirax and Zyban.

573. The drugs manufactured by J&J and distributed through the Together Card Program include, but may not be limited to: Aciphex, Bicitra, Concerta, Ditropan XL, Duragesic, Ehmiron, Erycette, Flexeril, Floxin, Grifulvin V, Haldol, Levaquin, Monistat-Derm, Mycelex, Neutraphos, Pancrease, Parafon Forte DSC, Polycitra, Regranex, Reminyl, Renova, Retin-A Micro, Risperdal, Spectrazole, Sporanox, Terazol, Tolectin, Topamax, Tylenol with Codeine, Tylox, Ultracet, Ultram, Vascor and Vermox.

574. The drugs manufactured by Novartis and distributed through the Together Card Program include, but may not be limited to: Clozaril, CombiPatch, Comtan, Diovan, Diovan HCT, Elidel, Estraderm, Exelon, Famvir, Femara, Focalin, Lamisil, Lescol/Lescol XL, Lotensin, Lotensin HCT, Miacalcin Injection & Nasal Spray, Parlodel, Rescula, Ritalin Hydrochloride, Ritalin LA, Starlix, Tegretol, Tegretol-XR, Trileptal, Vivelle/Vivelle-Dot, Voltaren Ophthalmic, Zaditor, and Zelnorm.

575. The drugs manufactured by TAP and distributed through the Together Card Program, include but may not be limited to: Prevacid.

D. Marketing of the Together Card Program

576. The Founding Together Card Defendants encouraged immediate and widespread enrollment in the Together Card Program:

The individual companies' sales forces, which total more than 30,000 representatives, will assist in making enrollment materials available through participating pharmacies, physicians' offices and community centers.

The members of Together Rx are committed to maximizing enrollment in the Together Rx Card and at the same time to identifying patients who may qualify for their independent [patient assistance programs].

577. According to the Founding Together Card Defendants, “[p]harmacies across the country . . . have shown strong support for the [Together Card]. In addition to accepting the card at their retail outlets in communities across America, participating pharmacies have made the commitment to pass through direct to the patient 100% of the savings being offered by the pharmaceutical companies.”

578. The website of the alliance, www.together-rx.com, addresses enrollment, eligibility and use issues pertaining to the Together Card:

Enrollment in Together Rx is free. There is no fee to apply for or to receive the Card. Enrollees apply for the Together Rx Card by completing and mailing a postage-paid application available from Together Rx.

Together Rx Card users present the Card, along with their doctor's prescription (or when obtaining a refill), at a participating pharmacy. Card users are to receive savings right at the pharmacy counter. The Card could be used at participating retail pharmacies beginning June 2002.

Approximately 11 million Medicare enrollees may be eligible for Together Rx. Enrollees must: (1) be a Medicare enrollee; (2) have an annual income of less than \$28,000 (individuals) or \$38,000 (couples); and (3) not have public or private prescription drug coverage. In Alaska, enrollees must have an annual income of less than \$35,000 (single) or \$48,000 (couple). In Hawaii, enrollees must have an annual income less than \$33,000 (single) or \$44,000 (couple). Households of three or more are to contact Together Rx for eligibility information.

579. The Founding Together Card Defendants, in their April 10, 2002 press release and at www.together-rx.com, claim participants in the Together Card Program will save “approximately 20-40% off the amount [they] usually pay for prescriptions and, in many cases, substantially more.” The Founding Together Card Defendants also note:

This range of savings reflects the mix of savings programs presently offered by each company and is subject to change. Each company sets its own levels of savings independently, with a minimum savings of 15% off its list price to wholesalers [AWP]. Actual consumer savings may vary depending on a pharmacy’s customary pricing for a specific medicine and each company’s saving program requirements, including any minimum quantity requirements. Each company independently determines which products are included in the savings program. Products covered are subject to change. [Emphasis added].

580. The Founding Together Card Defendants’ promotional efforts yielded an immediate and tremendous response from seniors. According to another press release, by July 29, 2002, enrollment in the Together Card Program had reached 118,000. The Founding Together Card Defendants encouraged “other pharmaceutical companies to join this effort and help broaden the number of products offered.” By November of 2002, enrollment was estimated at nearly 400,000. Just weeks earlier, on October 3, 2002, a spokesman for BMS claimed that the Together Card had already saved seniors \$6.4 million on prescription drugs since June of 2002.

581. On their Together Rx website, the Together Card Defendants offered the following response to the question “Why are all these pharmaceutical companies doing this?”:

The participating companies are committed to providing seniors and other eligible Medicare patients with broader access to savings

on many medications with convenience of one card. Together Rx is designed to fill a gap in the system for the short term. The real solution is implementation of Medicare reform, including a prescription drug benefit.

582. The current website continues to promise savings:

Savings and medicines. Together.

Save big on many commonly prescribed medicines.

Together RX is a prescription savings program that offers a free, easy way to save approximately 20% to 40% on brand-name medicines and, in many cases, much more (depending on your prescription and pharmacy). You can save on more than 170 medicines (click here to see the entire list). And some pharmacies even offer savings on generics.

583. On February 3, 2003, Together Rx informed pharmaceutical industry publication *The Pink Sheet* that Together Card enrollment had recently surpassed 570,000 members. Together Rx also indicated that it had targeted 2003 enrollment at 1.5 million members.

E. The Together Card Defendants' Conspiracy to Fix the AWP Spread of the Together Card Drugs

584. Although claiming its purpose was to help provide Medicare beneficiaries with "broader access to savings" on prescription pharmaceuticals, the Together Card Defendants used their alliance and the Together Card Program to raise, fix, maintain and/or stabilize the AWP spread for their prescription drugs and maximize profits.

585. When the Together Card Defendants aligned themselves in order to offer a combined drug discount card for elderly Americans, they perceived a significant problem with a discount card effort — elderly and poor Americans *might actually end up paying less* for their prescription drugs. Although the Together Card Defendants did not necessarily object to elderly and poor Americans paying less for drugs, they did not want to bear that expense themselves. The quandary continued, however, because others in the distribution chain — major retail pharmacy chains, PBMs, wholesalers — similarly did not wish to bear the cost of reduced expenditures by elderly and poor Americans. Put differently, the discounts could not be borne by retail pharmacists or wholesalers (given their claim to already being squeezed on margin).

586. Moreover, administration of the Together Card Program would itself carry some cost. While the Together Card Defendants wished the publicity attendant on providing a “free” discount drug card, they did not wish to bear the financial administrative costs for the program, and they needed to persuade retail pharmacists to participate without incurring product or administrative costs.

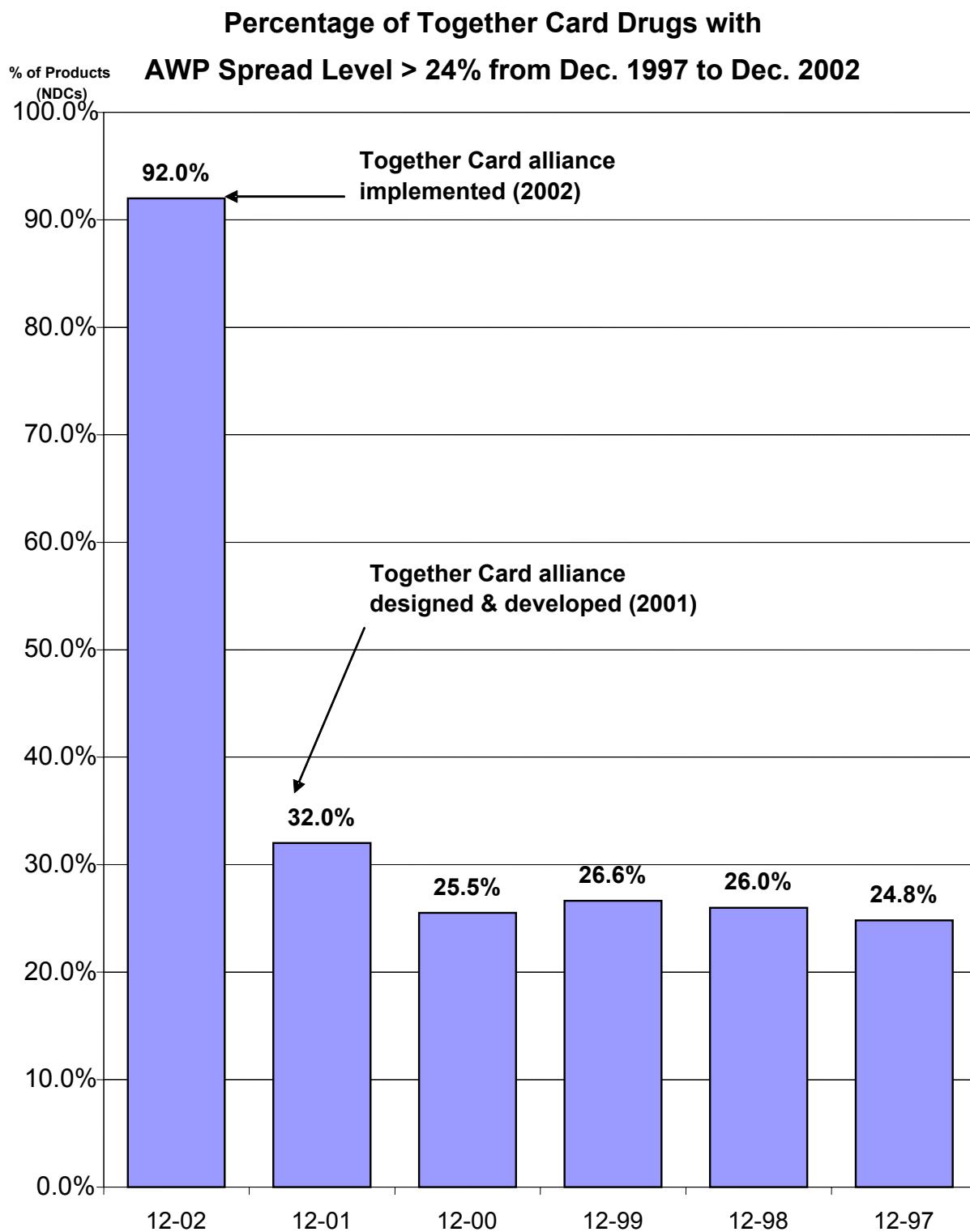
587. As a result of their desire to avoid the financial burden of the Together Rx Program, the Together Card Defendants conspired and agreed to simply impose the burden of the Together Card Drugs right back upon consumers by raising reimbursement or end payor prices (typically based on AWPs) in relation to actual cost to wholesalers, pharmacies and mail order companies (typically tied in some way to WAC, although subject to discounting and rebates).

588. Specifically, in conjunction with the establishment and management of their Together Card Program, the Together Card Defendants agreed to raise, fix, maintain and/or stabilize the AWP “spread” on nearly every one of the 170+ drugs included in the Together Card Program. The Together Card Defendants increased the AWP spread on most of their Together Card Drugs – across many therapeutic classes and product lines. The 170+ Together Card Drugs account for approximately 900 pharmaceutical line-items (the line-items reflecting the 170+ drugs in different forms, sizes and dosages). The AWP spread for over 80% of these line-items were increased.

589. Put simply, by increasing the difference between posted AWPs and posted WAC, the Together Card Defendants created spread dollars available to others in the distribution chain as an incentive to participate in the program — all to the detriment, and only to the detriment, of end payors (and enrollees).

590. Prior to the formation of the Together Rx alliance, the AWPs for the Together Card Drugs reflected an AWP pricing spread of roughly 20% (AWP – WAC/WAC). Following formation of the alliance, the Together Card Defendants increased the AWP spreads for these

same drugs to a range of 21-26%, whether sold through or outside of the Together Card Program. As reflected by the chart below, the percentage of all Together Card Drugs manufactured by the Together Card Defendants with an AWP spread level greater than 24% increased from 25.5 % in 2000 – prior to the development and implementation of the Together Card Program – to 92% by 2002, as depicted by the following chart.



591. An increase in the AWP spread was often achieved through an increase in the AWP of a Together Card Drug. An increase in AWP directly results in higher prices to Plaintiffs and the Nationwide End Payor Together Card Class. For example, in the case of AstraZeneca's Prilosec (as reflected in the chart below), the AWP spread increase raised the AWP for that drug by \$295.72. The following chart reflects, for a single drug manufactured by each Founding Together Card Defendant, the AWP spread increase and related AWP increase which occurred as a result of the Together Card Program.

Together Card Defendant	Together Card Drug	AWP Before Alliance	WAC Before Alliance	AWP Spread Before Alliance	AWP After Alliance	WAC After Alliance	AWP Spread After Alliance
Abbott	Biaxin 500 mg #60	\$396.72	\$334.08	18.8%	\$437.98	\$350.38	25%
AstraZeneca	Prilosec 40 mg #1000	\$6,171.66	\$5,143.05	20%	\$6,621.67	\$5,297.34	25%
Aventis	Allegra 60 mg #100	\$118.36	\$98.63	20%	\$123.29	\$98.63	25%
BMS	Tequin 400 mg #100	\$818.86	\$682.27	20%	\$895.48	\$716.38	25%
GSK	Combivir #100	\$1,241.26	\$1,034.38	20%	\$1,370.55	\$1,096.44	25%
J&J (Janssen)	Risperdal 2 mg #500	\$2,320.10	\$1,933.42	20%	\$2,535.20	\$2,028.16	25%
Novartis	Exelon 2 mg/ml	\$246.96	\$205.80	20%	\$267.29	\$213.83	25%

Almost all of the Together Card Drugs experienced similar AWP spread increases and related AWP increases.

592. The Together Card Defendants' increases in AWP spreads occurred in 2001 and 2002. The effectively simultaneous timing of the Together Card Defendants' increases in AWP spreads is unprecedented in terms of scope (i.e. number of products per manufacturer and number of manufacturers within the pharmaceutical industry). The Together Card Defendants' increases in AWP spread for the Together Card Drugs are not consistent with competitive conduct.

593. The Together Card Defendants' conduct is also inconsistent with their alleged motive to make prescription drugs more affordable to Medicare recipients by offering discounts on prescription prices. Indeed, the Together Card Defendants' immediate increase of the AWP spread on their Together Card Drugs diluted any meaningful discount for the relatively small number of eligible consumers and raised the price for other consumers significantly beyond what was charged prior to the Together Card Defendants' formation of the alliance.

594. The Together Card Defendants' conspiracy — agreeing to raise, fix, maintain and/or stabilize the AWP spread of their Together Card Drugs under the guise of a discount program — directly caused Plaintiffs to pay substantially more for those drugs than they would have paid if the Together Card Defendants had not engaged in their illegal conduct.

VIII. CLASS ACTION ALLEGATIONS FOR THE AWP PAYOR SCHEME

595. Plaintiffs bring this action pursuant to Rule 23 of the Federal Rules of Civil Procedure, on behalf of themselves and two Classes comprised of:

AWP Payor Class:

All persons or entities who, for purposes other than resale and during the Class Period, paid any portion of the purchase for a prescription drug manufactured by a Defendant Drug Manufacturer (as identified in Appendix A) at a price calculated by reference to the published AWP during the Class Period.¹¹

Sub-Class: The PBM Third-Party Payor Class:

All Third-Party Payors that, during the Class Period, contracted with a PBM to provide to its participants a prescription drug manufactured by a Defendant Drug Manufacturer and identified in Appendix A.

Excluded from the Classes are (a) each Defendant and any entity in which any Defendant has a controlling interest, and their legal representatives, officers, directors, assignees and successors;

¹¹ Plaintiffs reserve the right to modify the Class Definition based on class related discovery and/or merits discovery.

(b) any co-conspirators; and (c) any governmental entities who purchased such drugs during the Class Period.

596. The Class Period is January 1, 1991 to the present.

597. The Class consists of numerous individuals and entities throughout the United States, making individual joinder impractical, in satisfaction of Rule 23(a) (1). The disposition of the claims of the Class Members in a single class action will provide substantial benefits to all parties and to the Court.

598. The claims of the representative Plaintiffs are typical of the claims of the Class, as required by Rule 23(a) (3), in that the representative Plaintiffs include people and entities who, like all Class Members, purchased the AWPs at inflated prices based on AWPs. Such representative Plaintiffs, like all Class Members, have been damaged by Defendants' misconduct because, among other things, they paid prices for these drugs that were higher than they would have been but for Defendants' improper actions and have had medical providers make pharmacy decisions based on economic factors as opposed to purely medical factors.

599. The Class representatives for the Classes are all of the plaintiffs.

600. The factual and legal bases of each Defendant's misconduct are common to the Class Members and represent a common thread of fraud and other misconduct resulting in injury to Plaintiffs and members of the Class.

601. There are many questions of law and fact common to Plaintiffs and the Class, and those questions predominate over any questions that may affect individual Class Members, within the meaning of and fulfilling Rules 23(a) (2) and 23(b) (3). Common questions of law and fact include, but are not limited to, the following:

a. Whether Defendants engaged in a fraudulent and/or deceptive scheme of improperly inflating the AWPs for the Drugs identified in Appendix A used by Plaintiffs and Class Members as the basis for reimbursement;

- b. Whether Defendants artificially inflated the AWPs for these drugs;
- c. Whether it was the policy and practice of Defendants to prepare marketing and sales materials that contained comparisons of the published AWPs and the spreads available;
- d. Whether Defendants provided free samples of the AWPIDs to providers, and whether Defendants instructed them to bill Plaintiffs and the Class for those free samples;
- e. Whether Defendants' provision of free samples to providers, with the intent that the providers bill Plaintiffs and the Class for the free samples, was unlawful;
- f. Whether Defendants paid financial inducements to providers and other intermediaries, with the effect of lowering their costs for AWPIDs;
- g. Whether Defendants engaged in a pattern and practice of paying illegal kickbacks, disguised as free goods, rebates, consulting fees, junkets and education grants to providers and other intermediaries;
- h. Whether AWPs are used as a benchmark for negotiating payments by Third-Party Payors for the AWPIDs;
- i. Whether Defendants engaged in a pattern and practice that caused Plaintiffs and Class Members to make inflated payments for the AWPIDs;.
- j. Whether Defendants engaged in a pattern of deceptive and/or fraudulent activity intended to defraud Plaintiffs and the Class members;
- k. Whether Defendants formed enterprises for the purpose of carrying out the AWP Scheme;
- l. Whether Defendants used the U.S. mails and interstate wire facilities to carry out the AWP Scheme;
- m. Whether Defendants' conduct violated RICO;
- n. Whether Defendants are liable to Plaintiffs and the Class members for damages for conduct actionable under the various state consumer protection statutes.

602. Plaintiffs will fairly and adequately represent and protect the interests of the Class, as required by Rule 23(a)(4). Plaintiffs have retained counsel with substantial experience in prosecuting nationwide consumer class actions. Plaintiffs and their counsel are committed to vigorously prosecuting this action on behalf of the Class, and have the financial resources to do so. Neither Plaintiffs nor their counsel have any interest adverse to those of the Class.

603. Plaintiffs and members of the Class have all suffered, and will continue to suffer, harm and damages as a result of Defendants' unlawful and wrongful conduct. A class action is superior to other available methods for the fair and efficient adjudication of this controversy under Rule 23(b)(3). Absent a class action, most members of the Class likely would find the cost of litigating their claims to be prohibitive, and will have no effective remedy at law. The class treatment of common questions of law and fact is also superior to multiple individual actions or piecemeal litigation in that it conserves the resources of the Courts and the litigants, and promotes consistency and efficiency of adjudication. Additionally, Defendants have acted and failed to act on grounds generally applicable to Plaintiffs and the Class and require Court imposition of uniform relief to ensure compatible standards of conduct toward the Class, thereby making appropriate equitable relief to the Class as a whole within the meaning of Rules 23(b)(1) and (b)(2).

IX. CLASS ACTION ALLEGATIONS FOR THE TOGETHER CARD SCHEME

604. Plaintiffs bring this action pursuant to Rule 23 of the Federal Rules of Civil Procedure, on behalf of themselves and two classes ("the Classes"):

The Nationwide End Payor Together Card Class:

All person or entities in the United States and its territories who paid any portion of the purchase price for, or who reimbursed any portion of the purchase price of, a drug covered by the Together Rx Program on the basis, in whole or in part, on the published average wholesale price during the time period January 1, 2002 up to and including the present.

605. In the event the Court rules that plaintiffs do not have standing under the antitrust laws, an alternate class to that set forth above is:

The Indirect Purchaser States End Payor Together Card Class:

All persons or entities in the indirect purchaser states who paid any portion of the purchase price for, or who reimbursed any portion of the purchase price of, a drug covered by the Together Rx Program on the basis, in whole or in part, on the published average wholesale price during the time period January 1, 2002 up to and including the present.

Excluded from the Classes are (a) each Defendant and any entity in which any Defendant has a controlling interest, and their legal representatives, officers, directors, assignees and successors; (b) any co-conspirators; and (c) any governmental entities who purchased such drugs during the Class Period.

606. The Class representatives for the Nationwide End Payor Together Card Class are all of the plaintiffs, excluding the association plaintiffs.

607. The Class representatives for the Indirect Purchaser States End Payor Together Card Class are all plaintiffs, excluding the association plaintiffs.

608. Each of the Class Representatives purchased the Together Card Drugs identified herein.

609. The Class Period is January 1, 2002 to the present.

610. The Classes consist of numerous individuals and entities throughout the United States, making individual joinder impractical, in satisfaction of Rule 23(a)(1). The disposition of the claims of the Class Members in a single class action will provide substantial benefits to all parties and to the Court.

611. The claims of the representative Plaintiffs are typical of the claims of the Classes, as required by Rule 23(a)(3), in that the representative Plaintiffs include people and entities who, like all Class Members, purchased the Together Card Drugs in, our outside of, the Together Card Program. Such representative Plaintiffs, like all Class Members, have been damaged by

Defendants' misconduct because, among other things, they paid prices for the Together Card Drugs that were higher than they would have been but for Defendants' improper actions.

612. The factual and legal bases of each Defendant's misconduct are common to the Class Members and represent a common thread of conspiracy and other misconduct resulting in injury to Plaintiffs and member of the Classes.

613. There are many questions of law and fact common to Plaintiffs and the Classes, and those questions predominate over any questions that may affect individual Class Members, within the meaning of and fulfilling Rules 23(a)(2) and 23(b)(3). Common questions of law and fact include, but are not limited to, the following:

- (a) Whether Defendants engaged in a combination or conspiracy to raise, fix, stabilize and maintain the AWP spreads for the Together Card Drugs;
- (b) The duration and extent of the combination or conspiracy alleged herein;
- (c) Whether Defendants, and each of them, was a participant in the combination or conspiracy alleged herein;
- (d) Whether the alleged combination and conspiracy violated Section 1 of the Sherman Act;
- (e) Whether the alleged combination and conspiracy violated the antitrust statutes of the Indirect Purchaser States;
- (f) Whether the Together Card Defendants engaged in a pattern and practice that caused Plaintiffs and Together Card Class Members to make inflated payments for the Together Card Drugs;
- (g) Whether the Together Card Defendants formed an enterprise for the purpose of carrying out their conspiracy and agreement;
- (h) Whether the Together Card Defendants used the U.S. mails and interstate wire facilities to carry out their conspiracy and agreement; and

(i) Whether the Together Card Defendants' conduct violated RICO; and
(j) Whether Defendants engaged in a pattern and practice that caused Plaintiffs and Class Members to make inflated payments for the Together Card Drugs.

614. Plaintiffs will fairly and adequately represent and protect the interests of the Classes, as required by Rule 23(a)(4). Plaintiffs have retained counsel with substantial experience in prosecuting nationwide consumer class actions. Plaintiffs and their counsel are committed to vigorously prosecuting this action on behalf of the Classes, and have the financial resources to do so. Neither Plaintiffs nor their counsel have any interest adverse to those of the Classes.

615. Plaintiffs and members of the Classes have all suffered, and will continue to suffer, harm and damages as a result of Defendants' unlawful and wrongful conduct. A class action is superior to other available methods for the fair and efficient adjudication of this controversy under Rule 23(b)(3). Absent a class action, most members of the Classes likely would find the cost of litigating their claims to be prohibitive, and will have no effective remedy at law. The class treatment of common questions of law and fact is also superior to multiple individual actions or piecemeal litigation in that it conserves the resources of the Courts and the litigants, and promotes consistency and efficiency of adjudication.

616. The Nationwide Enrollees Class and the Nationwide End Payor Together Card Class have both suffered antitrust injury within the meaning of federal antitrust laws and have standing to sue for damages under Section 1 of the Sherman Act and Section IV of the Clayton Act. The Together Card Class Representatives and the National Together Card Enrollee Class are persons who have suffered injury to business or property by reason of a violation of Section 1 of the Sherman Act. Similarly, the End Payor Class Representatives and the Nationwide End Payor Together Card Class are persons who have suffered injury to business or property by reason of a violation of Section 1 of the Sherman Act. Members of each of the Nationwide

Classes are consumers or business entities that have standing to seek a Section IV Clayton Act remedy reflecting the increase in the purchase price or reimbursement rate for applicable drugs that is attributable to the price fixing conspiracy of the Defendants.

617. Members of the two Nationwide Classes are the directly injured persons. The conspiracy alleged herein is a conspiracy to effectuate over-reimbursement or end payor purchase cost in relation to actual transaction cost through intermediaries in the drug distribution channels. The conspiracy alleged here is *not* that initial actual prices to those in the distribution chain but passed on and eventually imposed upon consumers and other end payors; the opposite is alleged here. Here, the conspiracy alleged is that the end payor reimbursement for purchase price benchmark was secretly and unlawfully inflated, thereby enabling over reimbursement and over payments to all of those in the distribution chain, including retail pharmacies, mail order companies, PBMs and manufacturers. None of those in the distribution chain actually pay the cost imposed by the reimbursement fix alleged herein. The first and only party to bear this cost are the end payors, be they uninsured consumers, health plans or insurance companies.

618. This case poses no likelihood of duplicative recovery. The conspiracy alleged does not even theoretically present potential damage to intermediaries in the retail or mail order drug distribution channels. Instead, only one level of injured persons is alleged here – the end payors for applicable drugs whose purchases were made, in whole or in part, on the basis of the published average wholesale price for the applicable drugs.

COUNT I¹²

VIOLATIONS OF 18 U.S.C. § 1962(C)

**(AGAINST DEFENDANT DRUG MANUFACTURERS IDENTIFIED
HEREIN FOR UNLAWFUL CONDUCT ASSOCIATED WITH
AWPID DRUGS)**

619. Plaintiffs, on behalf of themselves and all others similarly situated, reallege and incorporate herein by reference each of the allegations contained in the preceding paragraphs of this Amended Complaint.

620. This Count, which alleges violations of Section 1962(c) of RICO, 18 U.S.C. § 1962(c), is asserted against the Defendant Drug Manufacturers on behalf of the AWP classes with respect to all AWPID drugs not purchased through use of a PBM and includes drugs covered under Medicare Part B and those outside of Part B coverage. The pricing of all such AWPs was directly tied to the published AWPs

621. Plaintiffs, the members of Classes, and the Defendant Drug Manufacturers are each “persons,” as that term is defined in 18 U.S.C. § 1961(3).

622. The following publishers of pharmaceutical industry compendia that periodically publish the AWPs, both in printed and electronic media, for various dosages of drugs are each “persons,” as that term is defined in 18 U.S.C. § 1961(3): (a) **Thomson Medical Economics** (“Thomson Medical”) is a division of Thomson Corporation, a Delaware corporation with its principal place of business located at One Station Place, Stamford, Connecticut, and it is the publisher of the *Drug Topics Red Book* (the “Red Book”); (b) **First DataBank, Inc.**, (“First DataBank”) a Missouri corporation, with its principal place of business at 1111 Bayhill Drive, San Bruno, California, and it is the publisher of drug pricing information including, but not limited to, *American Druggist First Databank Annual Directory of Pharmaceuticals* and

¹² This Amended Complaint does not contain certain material struck or dismissed by the Court in its May 13, 2003 Memorandum and Order. For instance, many association plaintiffs and several RICO counts that were included in the MCC have not been included in this amended complaint in order to reduce the volume of an already lengthy pleading. However, plaintiffs incorporate by this reference, into this Complaint, material struck or dismissed by the Court in order to, if necessary, preserve appellate rights. Plaintiffs acknowledge that these allegations would be dismissed if reasserted.

Essential Directory of Pharmaceuticals, commonly referred to as the *Blue Book*; (c) and **Facts & Comparisons, Inc.**, (“Facts & Comparisons”) a division of Lippincott Williams & Wilkins, Inc., a Pennsylvania corporation which acquired all drug information reference products formerly published by Medi-Span, Inc. and which currently makes available drug pricing information, including, but not limited to, the Medi-Span *Master Drug Data Base*. These entities are sometimes collectively referred to herein as “the Publishers.”

623. At all relevant times, in violation of 18 U.S.C. § 1962(c), the Defendant Drug Manufacturers conducted the affairs of certain association-in-fact enterprises identified herein, the affairs of which affected interstate commerce through a pattern of racketeering activity.

The Manufacturer-Publisher Enterprises

624. For purposes of this claim, certain RICO “enterprises” are associations-in-fact consisting of (a) one of the Publishers that reported AWPs for AWPIDs, and (b) a Defendant Drug Manufacturer, including its directors, employees and agents. These associations-in-fact are sometimes collectively referred to herein as the “Manufacturer-Publisher Enterprises.” Each of the Manufacturer-Publisher Enterprises is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common or shared purposes of (a) publishing or otherwise disseminating pharmaceutical price information, which all too often includes disseminating false and misleading AWPs, (b) selling, purchasing, and administering AWPIDs to Plaintiffs and Class members, and (c) deriving profits from these activities. Each of the enterprises had a common purpose of perpetuating use of AWPs as a benchmark for reimbursement in the pharmaceutical industry, generally, and specifically for the drugs of that defendant. The manufacturing defendants have this as a purpose because without the AWP scheme, they would not be able to push the spread. The publishers agree to this scheme, because if they did not, the manufacturers could easily revert to the other methods of publishing prices or the publishers would have to independently investigate the AWP

at significant expense. The Publishers also have an economic incentive to merely report the AWPs provided to them by the manufacturers, because to do otherwise would require the Publishers to spend money to extensively survey actual sales prices in the market. By simply republishing what is submitted to them by the drug manufacturers, the Publishers save on expenses and consequently reap greater profits. Thus, each of the Manufacturer-Publisher Enterprises has a common purpose of perpetuating the use of AWPs as a benchmark for reimbursement in the pharmaceutical industry.

625. Each of the Manufacturer-Publisher Enterprises has a systemic linkage because there are contractual relationships, financial ties, and continuing coordination of activities between the Defendant Drug Manufacturer and the specific Publisher that are its associates. As to each of the Manufacturer-Publisher Enterprises, there is a common communication network by which the Defendant Drug Manufacturer and the specific Publisher share information on a regular basis. Typically this communication occurs by use of the wires and mails in which a manufacturer will instruct a publisher to list a certain AWP. As to each of the Manufacturer-Publisher Enterprises, the Defendant Drug Manufacturer and the specific Publisher functioned as a continuing unit. At all relevant times, each of the Manufacturer-Publisher Enterprises was operated by the specific Defendant Drug Manufacturer for criminal purposes, namely, carrying out the AWP Scheme.

626. At all relevant times, each one of the Publishers was aware of the Defendants Drug Manufacturers' AWP Scheme, was a knowing and willing participant in that scheme, and reaped profits from that scheme. Each of the publishing manufacturers is aware that the published AWPs are inflated. This awareness comes from the following sources: First, at some point prior to 1992 the publishers in many instances obtained AWPs themselves by survey. From their surveys of those in the distribution chain, they were and are aware that the reported AWPs were not accurate. Second, as various congressional bodies and government agencies

reported on AWP inflation, the Publishers did not change or challenge the self-reported AWPs, but continued blindly accepting the requested AWPs. Third, when the State of Texas began prosecuting Dey for its AWP practices, and when other states began focusing on Dey, the Publishers stopped accepting Dey's reported AWPs and published a different, far lower AWP. They withdraw from the Dey enterprise due to fear that they would be sued if they continued to publish Dey's false AWPs. This prompted a lawsuit by Dey alleging that the Publishers were treating Dey differently than they were treating all other manufacturers. In other words, Dey was complaining of the others being allowed to continue the scheme while it could not.

627. The foregoing evidences the Publishers willing participation in the enterprise; their common purpose in the AWP scheme; and their agreement to a structure wherein the manufacturers made decisions as to what AWPs would be reported. This structure was the basis in which each of the enterprises was structured and its affairs conducted. The only exception occurred when the Publishers, fearing litigation, refused to accept Dey's instructions. The Publishers were willing participants in the scheme because if the truth were revealed the entire AWP reporting system would collapse.

628. For purposes of this count, the Manufacturer-Publisher Enterprises are identified as follows:

(a) *The Abbott Manufacturer-Publisher Enterprises:* The Abbott Manufacturer-Publisher Enterprises are three separate associations-in-fact consisting of each of the Publishers that reported the AWPID AWPs that were provided to them by Abbott, and Abbott, including its directors, employees and agents: (1) the Abbott-Thomson Medical Enterprise; (2) the Abbott-First DataBank Enterprise; and (3) the Abbott-Facts & Comparisons Enterprise. Each of the Abbott Manufacturer-Publisher Enterprises is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common or shared

purposes of (a) publishing or otherwise disseminating false and misleading AWPs, (b) selling, purchasing, and administering AWPIDs to individual Plaintiffs and Class members and to participants in those Plaintiffs and Class members that comprise health and welfare plans, and (c) deriving profits from these activities. Each of the Abbott Manufacturer-Publisher Enterprises has a systemic linkage because there are contractual relationships, financial ties, and continuing coordination of activities between Abbott and Thomson Medical, Abbott and First DataBank, and Abbott and Facts & Comparisons. As to each of these Abbott Manufacturer-Publisher Enterprises, there is a common communication network by which Abbott and Thomson Medical, Abbott and First Data Bank, and Abbott and Facts & Comparisons share information on a regular basis. As to each of these Abbott-Manufacturer-Publisher Enterprises, Abbott and Thomson Medical, Abbott and First Data Bank, and Abbott and Facts & Comparisons functioned as continuing but separate units. At all relevant times, each of the Abbott Manufacturer-Publisher Enterprises was operated and conducted by Abbott for criminal purposes, namely, carrying out the AWP Scheme.

(b) *The Amgen Manufacturer-Publisher Enterprises:* The Amgen Manufacturer-Publisher Enterprises are three separate associations-in-fact consisting of each of the Publishers that reported the AWPID AWPs that were provided to them by Amgen, and Amgen, including its directors, employees and agents: (1) the Amgen-Thomson Medical Enterprise; (2) the Amgen-First DataBank Enterprise; and (3) the Amgen-Facts & Comparisons Enterprise. Each of the Amgen Manufacturer-Publisher Enterprises is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common or shared purposes of (a) publishing or otherwise disseminating false and misleading AWPs, (b) selling, purchasing, and administering AWPIDs to individual Plaintiffs and Class

members and to participants in those Plaintiffs and Class members that comprise health and welfare plans, and (c) deriving profits from these activities. Each of the Amgen Manufacturer-Publisher Enterprises has a systemic linkage because there are contractual relationships, financial ties, and continuing coordination of activities between Amgen and Thomson Medical, Abbott and First DataBank, and Abbott and Facts & Comparisons. As to each of these Amgen Manufacturer-Publisher Enterprises, there is a common communication network by which Amgen and Thomson Medical, Amgen and First Data Bank, and Amgen and Facts & Comparisons share information on a regular basis. As to each of these Amgen-Manufacturer-Publisher Enterprises, Amgen and Thomson Medical, Amgen and First Data Bank, and Amgen and Facts & Comparisons functioned as continuing but separate units. At all relevant times, each of the Amgen Manufacturer-Publisher Enterprises was operated and conducted by Amgen for criminal purposes, namely, carrying out the AWP Scheme.

(c) *The AstraZeneca Manufacturer-Publisher Enterprises:* The AstraZeneca Manufacturer-Publisher Enterprises are three separate associations-in-fact consisting of each of the Publishers that reported the AWPID AWPs that were provided to them by AstraZeneca, and AstraZeneca, including its directors, employees and agents: (1) the AstraZeneca -Thomson Medical Enterprise; (2) the AstraZeneca -First DataBank Enterprise; and (3) the AstraZeneca -Facts & Comparisons Enterprise. Each of the AstraZeneca Manufacturer-Publisher Enterprises is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common or shared purposes of (a) publishing or otherwise disseminating false and misleading AWPs, (b) selling, purchasing, and administering AWPIDs to individual Plaintiffs and Class members and to participants in those Plaintiffs and Class members that comprise health and welfare plans, and (c) deriving profits from

these activities. Each of the AstraZeneca Manufacturer-Publisher Enterprises has a systemic linkage because there are contractual relationships, financial ties, and continuing coordination of activities between AstraZeneca and Thomson Medical, AstraZeneca and First DataBank, and AstraZeneca and Facts & Comparisons. As to each of these AstraZeneca Manufacturer-Publisher Enterprises, there is a common communication network by which AstraZeneca and Thomson Medical, AstraZeneca and First Data Bank, and AstraZeneca and Facts & Comparisons share information on a regular basis. As to each of these AstraZeneca -Manufacturer-Publisher Enterprises, AstraZeneca and Thomson Medical, AstraZeneca and First Data Bank, and AstraZeneca and Facts & Comparisons functioned as continuing but separate units. At all relevant times, each of the AstraZeneca Manufacturer-Publisher Enterprises was operated and conducted by AstraZeneca for criminal purposes, namely, carrying out the AWP Scheme.

(d) *The Aventis Group Manufacturer-Publisher Enterprise:* The Aventis Group Manufacturer-Publisher Enterprises are three separate associations-in-fact consisting of each of the Publishers that reported the AWPID AWPs that were provided to them by Aventis Group, and Aventis Group, including its directors, employees and agents: (1) the Aventis Group -Thomson Medical Enterprise; (2) the Aventis Group-First DataBank Enterprise; and (3) the Aventis Group-Facts & Comparisons Enterprise. Each of the Aventis Group Manufacturer-Publisher Enterprises is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common or shared purposes of (a) publishing or otherwise disseminating false and misleading AWPs, (b) selling, purchasing, and administering AWPIDs to individual Plaintiffs and Class members and to participants in those Plaintiffs and Class members that comprise health and welfare plans, and (c) deriving profits from these activities. Each of the Aventis Group Manufacturer-Publisher Enterprises has a

systemic linkage because there are contractual relationships, financial ties, and continuing coordination of activities between Aventis Group and Thomson Medical, Aventis Group and First DataBank, and Aventis Group and Facts & Comparisons. As to each of these Aventis Group Manufacturer-Publisher Enterprises, there is a common communication network by which Aventis Group and Thomson Medical, Aventis Group and First Data Bank, and Aventis Group and Facts & Comparisons share information on a regular basis. As to each of these Aventis Group-Manufacturer-Publisher Enterprises, Aventis Group and Thomson Medical, Aventis Group and First Data Bank, and Aventis Group and Facts & Comparisons functioned as continuing but separate units. At all relevant times, each of the Aventis Group Manufacturer-Publisher Enterprises was operated and conducted by Aventis Group for criminal purposes, namely, carrying out the AWP Scheme.

(e) *The Baxter Manufacturer-Publisher Enterprises:* The Baxter Manufacturer-Publisher Enterprises are three separate associations-in-fact consisting of each of the Publishers that reported the AWPID AWPs that were provided to them by Baxter, and Baxter, including its directors, employees and agents: (1) the Baxter-Thomson Medical Enterprise; (2) the Baxter-First DataBank Enterprise; and (3) the Baxter Facts & Comparisons Enterprise. Each of the Baxter Manufacturer-Publisher Enterprises is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common or shared purposes of (a) publishing or otherwise disseminating false and misleading AWPs, (b) selling, purchasing, and administering AWPDs to individual Plaintiffs and Class 1 members and to participants in those Plaintiffs and Class 1 members that comprise health and welfare plans, and (c) deriving profits from these activities. Each of the Baxter Manufacturer-Publisher Enterprises has a systemic linkage because there are contractual relationships, financial ties, and continuing coordination of activities between Baxter and

Thomson Medical, Baxter and First DataBank, and Baxter and Facts & Comparisons. As to each of these Baxter Manufacturer-Publisher Enterprises, there is a common communication network by which Baxter and Thomson Medical, Baxter and First Data Bank, and Baxter and Facts & Comparisons share information on a regular basis. As to each of these Baxter-Manufacturer-Publisher Enterprises, Baxter and Thomson Medical, Baxter and First Data Bank, and Baxter and Facts & Comparisons functioned as continuing but separate units. At all relevant times, each of the Baxter Manufacturer-Publisher Enterprises was operated and conducted by Baxter for criminal purposes, namely, carrying out the AWP Scheme.

(f) *The Bayer Manufacturer-Publisher Enterprises:* The Bayer Manufacturer-Publisher Enterprises are three separate associations-in-fact consisting of each of the Publishers that reported the AWPID AWPs that were provided to them by Bayer, and Bayer, including its directors, employees and agents: (1) the Bayer-Thomson Medical Enterprise; (2) the Bayer-First DataBank Enterprise; and (3) the Bayer-Facts & Comparisons Enterprise. Each of the Bayer Manufacturer-Publisher Enterprises is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common or shared purposes of (a) publishing or otherwise disseminating false and misleading AWPs, (b) selling, purchasing, and administering AWPIDs to individual Plaintiffs and Class members and to participants in those Plaintiffs and Class members that comprise health and welfare plans, and (c) deriving profits from these activities. Each of the Bayer Manufacturer-Publisher Enterprises has a systemic linkage because there are contractual relationships, financial ties, and continuing coordination of activities between Bayer and Thomson Medical, Bayer and First DataBank, and Bayer and Facts & Comparisons. As to each of these Bayer Manufacturer-Publisher Enterprises, there is a common communication network

by which Bayer and Thomson Medical, Bayer and First Data Bank, and Bayer and Facts & Comparisons share information on a regular basis. As to each of these Bayer Manufacturer-Publisher Enterprises, Bayer and Thomson Medical, Bayer and First Data Bank, and Bayer and Facts & Comparisons functioned as continuing but separate units. At all relevant times, each of the Bayer Manufacturer-Publisher Enterprises was operated and conducted by Bayer for criminal purposes, namely, carrying out the AWP Scheme.

(g) *The Boehringer Group Manufacturer-Publisher Enterprises:* The Boehringer Group Manufacturer-Publisher Enterprises are three separate associations-in-fact consisting of each of the Publishers that reported the AWPID AWPs that were provided to them by Boehringer Group, and Boehringer Group, including its directors, employees and agents: (1) the Boehringer Group-Thomson Medical Enterprise; (2) the Boehringer Group-First DataBank Enterprise; and (3) the Boehringer Group-Facts & Comparisons Enterprise. Each of the Boehringer Group Manufacturer-Publisher Enterprises is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common or shared purposes of (a) publishing or otherwise disseminating false and misleading AWPs, (b) selling, purchasing, and administering AWPDs to individual Plaintiffs and Class members and to participants in those Plaintiffs and Class members that comprise health and welfare plans, and (c) deriving profits from these activities. Each of the Boehringer Group Manufacturer-Publisher Enterprises has a systemic linkage because there are contractual relationships, financial ties, and continuing coordination of activities between Boehringer Group and Thomson Medical, Boehringer Group and First DataBank, and Boehringer Group and Facts & Comparisons. As to each of these Boehringer Group Manufacturer-Publisher Enterprises, there is a common communication network by which Boehringer Group and Thomson Medical, Boehringer Group and First Data Bank,

and Boehringer Group and Facts & Comparisons share information on a regular basis. As to each of these Boehringer Group Manufacturer-Publisher Enterprises, Boehringer Group and Thomson Medical, Boehringer Group and First Data Bank, and Boehringer Group and Facts & Comparisons functioned as continuing but separate units. At all relevant times, each of the Boehringer Group Manufacturer-Publisher Enterprises was operated and conducted by Boehringer Group for criminal purposes, namely, carrying out the AWP Scheme.

(h) *The Braun Manufacturer-Publisher Enterprises:* The Braun Manufacturer-Publisher Enterprises are three separate associations-in-fact consisting of each of the Publishers that reported the AWPID AWPs that were provided to them by Braun, and Braun, including its directors, employees and agents: (1) the Braun-Thomson Medical Enterprise; (2) the Braun-First DataBank Enterprise; and (3) the Braun-Facts & Comparisons Enterprise. Each of the Braun Manufacturer-Publisher Enterprises is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common or shared purposes of (a) publishing or otherwise disseminating false and misleading AWPs, (b) selling, purchasing, and administering AWPIDs to individual Plaintiffs and Class members and to participants in those Plaintiffs and Class members that comprise health and welfare plans, and (c) deriving profits from these activities. Each of the Braun Manufacturer-Publisher Enterprises has a systemic linkage because there are contractual relationships, financial ties, and continuing coordination of activities between Braun and Thomson Medical, Braun and First DataBank, and Braun and Facts & Comparisons. As to each of these Braun Manufacturer-Publisher Enterprises, there is a common communication network by which Braun and Thomson Medical, Braun and First Data Bank, and Braun and Facts & Comparisons share information on a regular basis. As to each of these Braun

Manufacturer-Publisher Enterprises, Braun and Thomson Medical, Braun and First Data Bank, and Braun and Facts & Comparisons functioned as continuing but separate units. At all relevant times, each of the Braun Manufacturer-Publisher Enterprises was operated and conducted by Braun for criminal purposes, namely, carrying out the AWP Scheme.

(i) *The BMS Group Manufacturer-Publisher Enterprises:* The BMS Group Manufacturer-Publisher Enterprises are three separate associations-in-fact consisting of each of the Publishers that reported the AWPID AWPs that were provided to them by BMS Group, and BMS Group, including its directors, employees and agents: (1) the BMS Group-Thomson Medical Enterprise; (2) the BMS Group-First DataBank Enterprise; and (3) the BMS Group-Facts & Comparisons Enterprise. Each of the BMS Group Manufacturer-Publisher Enterprises is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common or shared purposes of (a) publishing or otherwise disseminating false and misleading AWPs, (b) selling, purchasing, and administering AWPIDs to individual Plaintiffs and Class members and to participants in those Plaintiffs and Class members that comprise health and welfare plans, and (c) deriving profits from these activities. Each of the BMS Group Manufacturer-Publisher Enterprises has a systemic linkage because there are contractual relationships, financial ties, and continuing coordination of activities between BMS Group and Thomson Medical, BMS Group and First DataBank, and BMS Group and Facts & Comparisons. As to each of these BMS Group Manufacturer-Publisher Enterprises, there is a common communication network by which BMS Group and Thomson Medical, BMS Group and First Data Bank, and BMS Group and Facts & Comparisons share information on a regular basis. As to each of these BMS Group Manufacturer-Publisher Enterprises, BMS Group and Thomson Medical, BMS Group and First Data Bank, and BMS Group and Facts & Comparisons

functioned as continuing but separate units. At all relevant times, each of the BMS Group Manufacturer-Publisher Enterprises was operated and conducted by BMS Group for criminal purposes, namely, carrying out the AWP Scheme.

(j) *The Dey Manufacturer-Publisher Enterprises:* The Dey Manufacturer-Publisher Enterprises are three separate associations-in-fact consisting of each of the Publishers that reported the AWPID AWPs that were provided to them by Dey, and Dey, including its directors, employees and agents: (1) the Dey-Thomson Medical Enterprise; (2) the Dey-First DataBank Enterprise; and (3) the Dey-Facts & Comparisons Enterprise. Each of the Dey Manufacturer-Publisher Enterprises is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common or shared purposes of (a) publishing or otherwise disseminating false and misleading AWPs, (b) selling, purchasing, and administering AWPDIs to individual Plaintiffs and Class members and to participants in those Plaintiffs and Class members that comprise health and welfare plans, and (c) deriving profits from these activities. Each of the Dey Manufacturer-Publisher Enterprises has a systemic linkage because there are contractual relationships, financial ties, and continuing coordination of activities between Dey and Thomson Medical, Dey and First DataBank, and Dey and Facts & Comparisons. As to each of these Dey Manufacturer-Publisher Enterprises, there is a common communication network by which Dey and Thomson Medical, Dey and First Data Bank, and Dey and Facts & Comparisons share information on a regular basis. As to each of these Dey Manufacturer-Publisher Enterprises, Dey and Thomson Medical, Dey and First Data Bank, and Dey and Facts & Comparisons functioned as continuing but separate units. At all relevant times, each of the Dey Manufacturer-Publisher Enterprises was operated and conducted by Dey for criminal purposes, namely, carrying out the AWP Scheme.

(k) *The Fujisawa Group Manufacturer-Publisher Enterprises:* The Fujisawa Group Manufacturer-Publisher Enterprises are three separate associations-in-fact consisting of each of the Publishers that reported the AWPID AWPs that were provided to them by Fujisawa Group, and Fujisawa Group, including its directors, employees and agents: (1) the Fujisawa Group-Thomson Medical Enterprise; (2) the Fujisawa Group-First DataBank Enterprise; and (3) the Fujisawa Group-Facts & Comparisons Enterprise. Each of the Fujisawa Group Manufacturer-Publisher Enterprises is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common or shared purposes of (a) publishing or otherwise disseminating false and misleading AWPs, (b) selling, purchasing, and administering AWPIDs to individual Plaintiffs and Class members and to participants in those Plaintiffs and Class members that comprise health and welfare plans, and (c) deriving profits from these activities. Each of the Fujisawa Group Manufacturer-Publisher Enterprises has a systemic linkage because there are contractual relationships, financial ties, and continuing coordination of activities between Fujisawa Group and Thomson Medical, Fujisawa Group and First DataBank, and Fujisawa Group and Facts & Comparisons. As to each of these Fujisawa Group Manufacturer-Publisher Enterprises, there is a common communication network by which Fujisawa Group and Thomson Medical, Fujisawa Group and First Data Bank, and Fujisawa Group and Facts & Comparisons share information on a regular basis. As to each of these Fujisawa Group Manufacturer-Publisher Enterprises, Fujisawa Group and Thomson Medical, Fujisawa Group and First Data Bank, and Fujisawa Group and Facts & Comparisons functioned as continuing but separate units. At all relevant times, each of the Fujisawa Group Manufacturer-Publisher Enterprises was operated and conducted by Dey for criminal purposes, namely, carrying out the AWP Scheme.

(l) *The GSK Group Manufacturer-Publisher Enterprises:* The GSK Group Manufacturer-Publisher Enterprises are three separate associations-in-fact consisting of each of the Publishers that reported the AWPID AWPs that were provided to them by GSK Group, and GSK Group, including its directors, employees and agents: (1) the GSK Group-Thomson Medical Enterprise; (2) the GSK Group-First DataBank Enterprise; and (3) the GSK Group-Facts & Comparisons Enterprise. Each of the GSK Group Manufacturer-Publisher Enterprises is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common or shared purposes of (a) publishing or otherwise disseminating false and misleading AWPs, (b) selling, purchasing, and administering AWPDIs to individual Plaintiffs and Class members and to participants in those Plaintiffs and Class members that comprise health and welfare plans, and (c) deriving profits from these activities. Each of the GSK Group Manufacturer-Publisher Enterprises has a systemic linkage because there are contractual relationships, financial ties, and continuing coordination of activities between GSK Group and Thomson Medical, GSK Group and First DataBank, and GSK Group and Facts & Comparisons. As to each of these GSK Group Manufacturer-Publisher Enterprises, there is a common communication network by which GSK Group and Thomson Medical, GSK Group and First Data Bank, and GSK Group and Facts & Comparisons share information on a regular basis. As to each of these GSK Group Manufacturer-Publisher Enterprises, GSK Group and Thomson Medical, GSK Group and First Data Bank, and GSK Group and Facts & Comparisons functioned as continuing but separate units. At all relevant times, each of the GSK Group Manufacturer-Publisher Enterprises was operated and conducted by GSK Group for criminal purposes, namely, carrying out the AWP Scheme.

(m) *The Hoffman-La Roche Manufacturer-Publisher Enterprises:* The Hoffman-La Roche Group Manufacturer-Publisher Enterprises are three separate associations-in-fact consisting of each of the Publishers that reported the AWPID AWPs that were provided to them by Hoffman-La Roche, and Hoffman-La Roche, including its directors, employees and agents: (1) the Hoffman-La Roche-Thomson Medical Enterprise; (2) the Hoffman-La Roche-First DataBank Enterprise; and (3) the Hoffman-La Roche-Facts & Comparisons Enterprise. Each of the Hoffman-La Roche Manufacturer-Publisher Enterprises is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common or shared purposes of (a) publishing or otherwise disseminating false and misleading AWPs, (b) selling, purchasing, and administering AWPIDs to individual Plaintiffs and Class members and to participants in those Plaintiffs and Class members that comprise health and welfare plans, and (c) deriving profits from these activities. Each of the Hoffman-La Roche Group Manufacturer-Publisher Enterprises has a systemic linkage because there are contractual relationships, financial ties, and continuing coordination of activities between Hoffman-La Roche and Thomson Medical, Hoffman-La Roche and First DataBank, and Hoffman-La Roche and Facts & Comparisons. As to each of these Hoffman-La Roche Manufacturer-Publisher Enterprises, there is a common communication network by which Hoffman-La Roche and Thomson Medical, Hoffman-La Roche and First Data Bank, and Hoffman-La Roche and Facts & Comparisons share information on a regular basis. As to each of these Hoffman-La Roche Manufacturer-Publisher Enterprises, Hoffman-La Roche and Thomson Medical, Hoffman-La Roche and First Data Bank, and Hoffman-La Roche and Facts & Comparisons functioned as continuing but separate units. At all relevant times, each of the Hoffman-La Roche

Manufacturer-Publisher Enterprises was operated and conducted by Hoffman-La Roche for criminal purposes, namely, carrying out the AWP Scheme.

(n) *The Immunex Manufacturer- Publisher Enterprises:* The Immunex Manufacturer-Publisher Enterprises are three separate associations-in-fact consisting of each of the Publishers that reported the AWPID AWPs that were provided to them by Immunex, and Immunex, including its directors, employees and agents: (1) the Immunex-La Roche-Thomson Medical Enterprise; (2) the Immunex-First DataBank Enterprise; and (3) the Immunex-Facts & Comparisons Enterprise. Each of the Immunex Manufacturer-Publisher Enterprises is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common or shared purposes of (a) publishing or otherwise disseminating false and misleading AWPs, (b) selling, purchasing, and administering AWPDIs to individual Plaintiffs and Class members and to participants in those Plaintiffs and Class members that comprise health and welfare plans, and (c) deriving profits from these activities. Each of the Immunex Manufacturer-Publisher Enterprises has a systemic linkage because there are contractual relationships, financial ties, and continuing coordination of activities between Immunex and Thomson Medical, Immunex and First DataBank, and Immunex and Facts & Comparisons. As to each of these Immunex Manufacturer-Publisher Enterprises, there is a common communication network by which Immunex and Thomson Medical, Immunex and First Data Bank, and Immunex and Facts & Comparisons share information on a regular basis. As to each of these Immunex Manufacturer-Publisher Enterprises, Immunex and Thomson Medical, Immunex and First Data Bank, and Immunex and Facts & Comparisons functioned as continuing but separate units. At all relevant times, each of the Immunex Manufacturer-Publisher

Enterprises was operated and conducted by Immunex for criminal purposes, namely, carrying out the AWP Scheme.

(o) *The Johnson & Johnson Group Manufacturer-Publisher Enterprise:* The Johnson & Johnson Group Manufacturer-Publisher Enterprises are three separate associations-in-fact consisting of each of the Publishers that reported the AWPID AWPs that were provided to them by Johnson & Johnson Group, and Johnson & Johnson Group, including its directors, employees and agents: (1) the Johnson & Johnson Group-La Roche-Thomson Medical Enterprise; (2) the Johnson & Johnson Group-First DataBank Enterprise; and (3) the Johnson & Johnson Group-Facts & Comparisons Enterprise. Each of the Johnson & Johnson Group Manufacturer-Publisher Enterprises is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common or shared purposes of (a) publishing or otherwise disseminating false and misleading AWPs, (b) selling, purchasing, and administering AWPDs to individual Plaintiffs and Class members and to participants in those Plaintiffs and Class members that comprise health and welfare plans, and (c) deriving profits from these activities. Each of the Johnson & Johnson Group Manufacturer-Publisher Enterprises has a systemic linkage because there are contractual relationships, financial ties, and continuing coordination of activities between Johnson & Johnson Group and Thomson Medical, Johnson & Johnson Group and First DataBank, and Johnson & Johnson Group and Facts & Comparisons. As to each of these Johnson & Johnson Group Manufacturer-Publisher Enterprises, there is a common communication network by which Johnson & Johnson Group and Thomson Medical, Johnson & Johnson Group and First Data Bank, and Johnson & Johnson Group and Facts & Comparisons share information on a regular basis. As to each of these Johnson & Johnson Group Manufacturer-Publisher Enterprises, Johnson & Johnson Group and Thomson Medical,

Johnson & Johnson Group and First Data Bank, and Johnson & Johnson Group and Facts & Comparisons functioned as continuing but separate units. At all relevant times, each of the Johnson & Johnson Group Manufacturer-Publisher Enterprises was operated and conducted by Johnson & Johnson Group for criminal purposes, namely, carrying out the AWP Scheme.

(p) *The Pfizer Manufacturer-Publisher Enterprises:* The Pfizer Manufacturer-Publisher Enterprises are three separate associations-in-fact consisting of each of the Publishers that reported the AWPID AWPs that were provided to them by Pfizer, and Pfizer, including its directors, employees and agents: (1) the Pfizer-La Roche-Thomson Medical Enterprise; (2) the Pfizer-First DataBank Enterprise; and (3) the Pfizer-Facts & Comparisons Enterprise. Each of the Pfizer Manufacturer-Publisher Enterprises is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common or shared purposes of (a) publishing or otherwise disseminating false and misleading AWPs, (b) selling, purchasing, and administering AWPDIs to individual Plaintiffs and Class members and to participants in those Plaintiffs and Class members that comprise health and welfare plans, and (c) deriving profits from these activities. Each of the Pfizer Manufacturer-Publisher Enterprises has a systemic linkage because there are contractual relationships, financial ties, and continuing coordination of activities between Pfizer and Thomson Medical, Pfizer and First DataBank, and Pfizer and Facts & Comparisons. As to each of these Pfizer Manufacturer-Publisher Enterprises, there is a common communication network by which Pfizer and Thomson Medical, Pfizer and First Data Bank, and Pfizer and Facts & Comparisons share information on a regular basis. As to each of these Pfizer Manufacturer-Publisher Enterprises, Pfizer and Thomson Medical, Pfizer and First Data Bank, and Pfizer and Facts & Comparisons functioned as continuing

but separate units. At all relevant times, each of the Pfizer Manufacturer-Publisher Enterprises was operated and conducted by Pfizer for criminal purposes, namely, carrying out the AWP Scheme.

(q) *The Pharmacia Group Manufacturer-Publisher Enterprises:* The Pharmacia Group Manufacturer-Publisher Enterprises are three separate associations-in-fact consisting of each of the Publishers that reported the AWPID AWPs that were provided to them by Pharmacia Group, and Pharmacia Group, including its directors, employees and agents: (1) the Pharmacia Group-Thomson Medical Enterprise; (2) the Pharmacia Group-First DataBank Enterprise; and (3) the Pharmacia Group-Facts & Comparisons Enterprise. Each of the Pharmacia Group Manufacturer-Publisher Enterprises is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common or shared purposes of (a) publishing or otherwise disseminating false and misleading AWPs, (b) selling, purchasing, and administering AWPDIs to individual Plaintiffs and Class members and to participants in those Plaintiffs and Class members that comprise health and welfare plans, and (c) deriving profits from these activities. Each of the Pharmacia Group Manufacturer-Publisher Enterprises has a systemic linkage because there are contractual relationships, financial ties, and continuing coordination of activities between Pharmacia Group and Thomson Medical, Pharmacia Group and First DataBank, and Pharmacia Group and Facts & Comparisons. As to each of these Pharmacia Group Manufacturer-Publisher Enterprises, there is a common communication network by which Pharmacia Group and Thomson Medical, Pharmacia Group and First Data Bank, and Pharmacia Group and Facts & Comparisons share information on a regular basis. As to each of these Pharmacia Group Manufacturer-Publisher Enterprises, Pharmacia Group and Thomson Medical, Pharmacia Group and First Data Bank, and Pharmacia Group and

Facts & Comparisons functioned as continuing but separate units. At all relevant times, each of the Pharmacia Group Manufacturer-Publisher Enterprises was operated and conducted by Pharmacia Group for criminal purposes, namely, carrying out the AWP Scheme.

(r) *The Schering-Plough Group Manufacturer-Publisher Enterprises:* The Schering-Plough Group Manufacturer-Publisher Enterprises are three separate associations-in-fact consisting of each of the Publishers that reported the AWPID AWPs that were provided to them by Schering-Plough Group, and Schering-Plough Group, including its directors, employees and agents: (1) the Schering-Plough Group-Thomson Medical Enterprise; (2) the Schering-Plough Group-First DataBank Enterprise; and (3) the Schering-Plough Group-Facts & Comparisons Enterprise. Each of the Schering-Plough Group Manufacturer-Publisher Enterprises is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common or shared purposes of (a) publishing or otherwise disseminating false and misleading AWPs, (b) selling, purchasing, and administering AWPDIs to individual Plaintiffs and Class members and to participants in those Plaintiffs and Class members that comprise health and welfare plans, and (c) deriving profits from these activities. Each of the Schering-Plough Group Manufacturer-Publisher Enterprises has a systemic linkage because there are contractual relationships, financial ties, and continuing coordination of activities between Schering-Plough Group and Thomson Medical, Schering-Plough Group and First DataBank, and Schering-Plough Group and Facts & Comparisons. As to each of these Schering-Plough Group Manufacturer-Publisher Enterprises, there is a common communication network by which Schering-Plough Group and Thomson Medical, Schering-Plough Group and First Data Bank, and Schering-Plough Group and Facts & Comparisons share information on a regular basis.

As to each of these Schering-Plough Group Manufacturer-Publisher Enterprises, Schering-Plough Group and Thomson Medical, Schering-Plough Group and First Data Bank, and Schering-Plough Group and Facts & Comparisons functioned as continuing but separate units. At all relevant times, each of the Schering-Plough Group Manufacturer-Publisher Enterprises was operated and conducted by Schering-Plough Group for criminal purposes, namely, carrying out the AWP Scheme.

(s) *The Sicor Group Manufacturer-Publisher Enterprises:* The Sicor Group Manufacturer-Publisher Enterprises are three separate associations-in-fact consisting of each of the Publishers that reported the AWPID AWPs that were provided to them by Sicor Group, and Sicor Group, including its directors, employees and agents: (1) the Sicor Group-Thomson Medical Enterprise; (2) the Sicor Group-First DataBank Enterprise; and (3) the Sicor Group-Facts & Comparisons Enterprise. Each of the Sicor Group Manufacturer-Publisher Enterprises is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common or shared purposes of (a) publishing or otherwise disseminating false and misleading AWPs, (b) selling, purchasing, and administering AWPDIs to individual Plaintiffs and Class members and to participants in those Plaintiffs and Class members that comprise health and welfare plans, and (c) deriving profits from these activities. Each of the Sicor Group Manufacturer-Publisher Enterprises has a systemic linkage because there are contractual relationships, financial ties, and continuing coordination of activities between Sicor Group and Thomson Medical, Sicor Group and First DataBank, and Sicor Group and Facts & Comparisons. As to each of these Sicor Group Manufacturer-Publisher Enterprises, there is a common communication network by which Sicor Group and Thomson Medical, Sicor Group and First Data Bank, and Sicor Group and Facts & Comparisons share information on a regular basis. As to each

of these Sicor Group Manufacturer-Publisher Enterprises, Sicor Group and Thomson Medical, Sicor Group and First Data Bank, and Sicor Group and Facts & Comparisons functioned as continuing but separate units. At all relevant times, each of the Sicor Group Manufacturer-Publisher Enterprises was operated and conducted by Sicor Group for criminal purposes, namely, carrying out the AWP Scheme.

(t) *The TAP Group Manufacturer-Publisher Enterprises:* The TAP Group Manufacturer-Publisher Enterprises are three separate associations-in-fact consisting of each of the Publishers that reported the AWPID AWPs that were provided to them by The TAP Group, and The TAP Group, including its directors, employees and agents: (1) the TAP Group-Thomson Medical Enterprise; (2) the TAP Group-First DataBank Enterprise; and (3) the TAP Group-Facts & Comparisons Enterprise. Each of the TAP Group Manufacturer-Publisher Enterprises is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common or shared purposes of (a) publishing or otherwise disseminating false and misleading AWPs, (b) selling, purchasing, and administering AWPDIs to individual Plaintiffs and Class members and to participants in those Plaintiffs and Class members that comprise health and welfare plans, and (c) deriving profits from these activities. Each of the TAP Group Manufacturer-Publisher Enterprises has a systemic linkage because there are contractual relationships, financial ties, and continuing coordination of activities between the TAP Group and Thomson Medical, the TAP Group and First DataBank, and the TAP Group and Facts & Comparisons. As to each of these TAP Group Manufacturer-Publisher Enterprises, there is a common communication network by which the TAP Group and Thomson Medical, the TAP Group and First Data Bank, and the TAP Group and Facts & Comparisons share information on a regular basis. As to each of these TAP Group Manufacturer-Publisher Enterprises, the TAP Group and

Thomson Medical, the TAP Group and First Data Bank, and the TAP Group and Facts & Comparisons functioned as continuing but separate units. At all relevant times, each of the TAP Group Manufacturer-Publisher Enterprises was operated and conducted by the TAP Group for criminal purposes, namely, carrying out the AWP Scheme.

(u) *The Watson Manufacturer-Publisher Enterprises:* The Watson Manufacturer-Publisher Enterprises are three separate associations-in-fact consisting of each of the Publishers that reported the AWPID AWPs that were provided to them by Watson, and Watson, including its directors, employees and agents: (1) the Watson-Thomson Medical Enterprise; (2) the Watson-First DataBank Enterprise; and (3) the Watson-Facts & Comparisons Enterprise. Each of the Watson Manufacturer-Publisher Enterprises is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common or shared purposes of (a) publishing or otherwise disseminating false and misleading AWPs, (b) selling, purchasing, and administering AWPDs to individual Plaintiffs and Class members and to participants in those Plaintiffs and Class members that comprise health and welfare plans, and (c) deriving profits from these activities. Each of the Watson Manufacturer-Publisher Enterprises has a systemic linkage because there are contractual relationships, financial ties, and continuing coordination of activities between Watson and Thomson Medical, Watson and First DataBank, and Watson and Facts & Comparisons. As to each of these Watson Manufacturer-Publisher Enterprises, there is a common communication network by which Watson and Thomson Medical, Watson and First Data Bank, and Watson and Facts & Comparisons share information on a regular basis. As to each of these Watson Manufacturer-Publisher Enterprises, Watson and Thomson Medical, Watson and First Data Bank, and Watson and Facts & Comparisons functioned as continuing but separate units. At all relevant times, each of the Watson

Manufacturer-Publisher Enterprises was operated and conducted by Watson for criminal purposes, namely, carrying out the AWP Scheme.

(v) *The Warrick Manufacturer-Publisher Enterprises:* The Warrick Manufacturer-Publisher Enterprises are three separate associations-in-fact consisting of each of the Publishers that reported the AWPID AWPs that were provided to them by Warrick, and Warrick, including its directors, employees and agents: (1) the Warrick-Thomson Medical Enterprise; (2) the Warrick-First DataBank Enterprise; and (3) the Warrick-Facts & Comparisons Enterprise. Each of the Warrick Manufacturer-Publisher Enterprises is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common or shared purposes of (a) publishing or otherwise disseminating false and misleading AWPs, (b) selling, purchasing, and administering AWPDIs to individual Plaintiffs and Class members and to participants in those Plaintiffs and Class members that comprise health and welfare plans, and (c) deriving profits from these activities. Each of the Warrick Manufacturer-Publisher Enterprises has a systemic linkage because there are contractual relationships, financial ties, and continuing coordination of activities between Warrick and Thomson Medical, Warrick and First DataBank, and Warrick and Facts & Comparisons. As to each of these Warrick Manufacturer-Publisher Enterprises, there is a common communication network by which Warrick and Thomson Medical, Warrick and First Data Bank, and Warrick and Facts & Comparisons share information on a regular basis. As to each of these Warrick Manufacturer-Publisher Enterprises, Warrick and Thomson Medical, Warrick and First Data Bank, and Warrick and Facts & Comparisons functioned as continuing but separate units. At all relevant times, each of the Warrick Manufacturer-Publisher Enterprises was operated and conducted by Warrick for criminal purposes, namely, carrying out the AWP Scheme.

The Defendant Drug Manufacturers' Use of the U.S. Mails and Interstate Wire Facilities

629. Each of the Manufacturer-Publisher Enterprises engaged in and affected interstate commerce because they engage in the following activities across state boundaries: The transmission and publication of false and misleading information concerning AWPs; the sale, purchase and/or administration of AWPIDs; and/or the transmission and/or receipt of sales and marketing literature; and/or the transmission and/or receipt of invoices, statements and payments related to the use or administration of AWPIDs.

630. During the Class Period, the Defendants Drug Manufacturers' illegal conduct and wrongful practices were carried out by an array of employees, working across state boundaries, who necessarily relied upon frequent transfers of documents and information, products and funds by the U.S. mails and interstate wire facilities.

631. The nature and pervasiveness of the Defendant Drug Manufacturers' AWP Scheme, which was orchestrated out of the corporate headquarters of the Defendant Drug Manufacturers, necessarily required those headquarters to communicate directly and frequently by the U.S. mails and by interstate wire facilities with the various local district managers overseeing the sales force(s), the numerous pharmaceutical sales representatives who, in turn, directly communicated with providers and employees who communicated with the Publishers.

632. Many of the precise dates of Defendant Drug Manufacturers' uses of the U.S. mails and interstate wire facilities (and corresponding RICO predicate acts of mail and wire fraud) have been hidden and cannot be alleged without access to these Defendants' books and records. Indeed, an essential part of the successful operation of the AWP Scheme alleged herein depended upon secrecy, and as alleged above, the Defendant Drug Manufacturers took deliberate steps to conceal their wrongdoing. However, Plaintiffs can generally describe the occasions on which the RICO predicate acts of mail fraud and wire fraud occurred, and how those acts were in furtherance of the AWP Scheme and do so below.

633. The Defendant Drug Manufacturers' use of the U.S. mails and interstate wire facilities to perpetrate the AWP Scheme involved thousands of communications throughout the Class Period including, *inter alia*:

- (a) Marketing materials about the AWPs for AWPs and the available spread, which were sent by the Defendant Drug Manufacturers to health care providers located across the country;
- (b) Written representations of the AWPs made by the Defendant Drug Manufacturers to the Publishers, which were made at least annually and in many cases several times during a single year;
- (c) Documents providing information or incentives designed to lessen the prices that health care providers paid for AWPs and/or to conceal those prices or the AWP Scheme alleged here;
- (d) Written communications, relating to rebates, kickbacks, or other financial inducements included, but not limited to, checks, as detailed herein;
- (e) Written and oral communications directed to U.S. Government agencies and private insurers that fraudulently misrepresented what the AWPs were, or that were intended to deter investigations into the true nature of the AWPs or to forestall changes to reimbursement based on something other than AWPs;
- (f) Written and oral communications with health insurers and patients, including Plaintiffs and members of the Class, inducing payments for the drugs that were made in reliance on AWPs; and
- (g) Receipts of money sent on tens of thousands of occasions through the U.S. mails and interstate wire facilities – the wrongful proceeds of the Defendant Drug Manufacturers' AWP Scheme.

(h) In addition to the above-referenced RICO predicate acts, it was foreseeable to the Defendant Drug Manufacturers that the Publishers would distribute their publications containing false AWPs through the U.S. mails and by interstate wire facilities. Further, the Defendant Drug Manufacturers' corporate headquarters have, in furtherance of the AWP Scheme, communicated through use of the U.S. mails and by interstate wire facilities with their various local headquarters or divisions. These uses of the U.S. mails include some of the documents referenced in this Amended Complaint.

Conduct of the RICO Enterprises' Affairs

634. During the Class Period, the Defendant Drug Manufacturers have exerted control over their Manufacturer-Publisher Enterprises and, in violation of Section 1962(c) of RICO, the Defendant Drug Manufacturers have conducted or participated in the conduct of the affairs of those RICO enterprises, directly or indirectly, in the following ways:

- (a) Each of the Defendant Drug Manufacturers has directly controlled the price for its AWPIDs;
- (b) Each of the Defendant Drug Manufacturers has directly controlled the AWPs that are reported by the Publishers;
- (c) Each of the Defendant Drug Manufacturers has directly controlled the creation and distribution of marketing, sales, and other materials used to inform health care providers nationwide of the profit potential of its AWPIDs;
- (d) Each of the Defendant Drug Manufacturers has controlled and participated in the affairs of its Manufacturer-Publisher Enterprises by using a fraudulent scheme to manufacture, market and sell its AWPIDs on the basis of AWPs that each of the Defendant Drug Manufacturers provides to the Publishers;

(e) Each of the Defendant Drug Manufacturers intended that each of the Publishers would (and did) distribute their publications containing false AWPs through the U.S. mails and by interstate wire facilities; and

(f) Each of the publishers has allowed these Defendants to exert control over their organizations knowing that the AWPs were inflated and were not real numbers. Each publisher did so because the reporting of AWPs was, and is, a major part of its business.

635. Each of the Manufacturer-Publisher Enterprises had a hierarchical decision-making structure headed by the respective Defendant Drug Manufacturer. The Defendant Drug Manufacturers issued instructions on how its AWPs were to be reported and each publisher accepted those instructions despite knowing of their falsity.

636. In violation of Section 1962(c) of RICO, each of the Defendant Drug Manufacturers have conducted the affairs of each of the Manufacturer-Publisher Enterprises with which they associated by reporting fraudulently inflated AWPs for AWPIDs that were then published by the Publishers and disseminated nationwide.

The Defendant Drug Manufacturers' Pattern of Racketeering Activity

637. Each of the Defendant Drug Manufacturers have conducted and participated in the affairs of their above-referenced Manufacturer-Publisher Enterprises through a pattern of racketeering activity, including acts that are indictable under 18 U.S.C. § 1341, relating to mail fraud, and 18 U.S.C. § 1343, relating to wire fraud. The Defendant Drug Manufacturers' pattern of racketeering likely involved thousands, if not hundreds of thousands, of separate instances of use of the U.S. mails or interstate wire facilities in furtherance of their AWP Scheme. Each of these fraudulent mailings and interstate wire transmissions constitutes a "racketeering activity" within the meaning of 18 U.S.C. § 1961(1)(B). Collectively, these violations constitute a "pattern of racketeering activity," within the meaning of 18 U.S.C. § 1961(5), in which the

Defendant Drug Manufacturers intended to defraud Plaintiffs, members of the Classes and other intended victims of the AWP Scheme.

638. The Defendants Drug Manufacturers' fraudulent and unlawful AWP Scheme consisted, in part, of deliberately overstating the AWPs for their AWPIDs, thereby creating a "spread" based on the inflated figure in order to induce others to advocate and favor that Defendant Drug Manufacturer's AWPIDs. Further, others would bill their clients for the Defendant Drug Manufacturers' AWPIDs based on the inflated AWPs, which did not reflect the true price paid for the AWPIDs.

639. The AWP Scheme was calculated and intentionally crafted to ensure that Plaintiffs and members of the Classes would be over-billed for the drugs. In designing and implementing the AWP Scheme, at all times the Defendant Drug Manufacturers were cognizant of the fact that those in the distribution chain who are not part of the industry rely on the integrity of the Defendant Drug Manufacturers in setting the AWPs, as reported by the Publishers.

639(a). Each of the plaintiffs, to the extent they purchased drugs outside of the PBM context, made purchases with the price being tied to AWP. *See ¶¶ 26-36.*

640. By intentionally and artificially inflating the AWPs, and by subsequently failing to disclose such practices to the individual patients, health plans and their insurers, the Defendant Drug Manufacturers engaged in a fraudulent and unlawful course of conduct constituting a pattern of racketeering activity.

641. The Defendant Drug Manufacturers' racketeering activities amounted to a common course of conduct, with similar pattern and purpose, intended to deceive Plaintiffs and members of the Classes. Each separate use of the U.S. mails and/or interstate wire facilities employed by the Defendant Drug Manufacturers was related, had similar intended purposes, involved similar participants and methods of execution, and had the same results affecting the same victims, including Plaintiffs and members of the Classes. Each of the Defendant Drug

Manufacturers has engaged in the pattern of racketeering activity for the purpose of conducting the ongoing business affairs of its particular Manufacturer-Publisher Enterprises.

The Defendant Drug Manufacturers' Motive

642. The Defendant Drug Manufacturers' motive in creating and operating the AWP Scheme and conducting the affairs of the Manufacturer-Publisher Enterprises described herein was to fraudulently obtain sales of and profits from their AWPIDs.

643. The AWP Scheme was designed to, and did, encourage others, including health care providers, to advocate the use of the Defendant Drug Manufacturers' AWPIDs. Thus, each of the Defendant Drug Manufacturers used the AWP Scheme to sell more of its drugs, thereby fraudulently gaining sales and market share and profits.

Damages Caused by the Defendant Drug Manufacturers' AWP Scheme

644. The Defendant Drug Manufacturers' violations of federal law and their pattern of racketeering activity have directly and proximately caused Plaintiffs and members of the Classes to be injured in their business or property because Plaintiffs and members of the Classes have paid many hundreds of millions of dollars in inflated reimbursements or other payments for AWPIDs.

645. The Defendant Drug Manufacturers sent billing statements through the U.S. mails or by interstate wire facilities and reported AWPs and other information by the same methods in furtherance of their AWP Scheme. Plaintiffs and members of the Classes have made inflated payments for AWPIDs based on and/or in reliance on reported and false AWPs.

646. Under the provisions of Section 1964(c) of RICO, the Defendant Drug Manufacturers are jointly and severally liable to Plaintiffs and members of the Classes for three times the damages that Plaintiffs and the Class members have sustained, plus the costs of bringing this suit, including reasonable attorneys' fees.

COUNT II

VIOLATIONS OF 18 U.S.C. § 1962(C)

(AGAINST DEFENDANT DRUG MANUFACTURERS IDENTIFIED HEREIN)

647. Plaintiffs, on behalf of themselves and all others similarly situated, reallege and incorporate herein by reference each of the allegations contained in the preceding paragraphs of this Amended Complaint.

648. This Count, which alleges violations of Section 1962(c) of RICO, 18 U.S.C. § 1962(c), is asserted against the Defendant Drug Manufacturers identified below on behalf of AWP Classes by the AWP Class representatives.

649. Plaintiffs, the members of Classes, and the Defendant Drug Manufacturers are each “persons,” as that term is defined in 18 U.S.C. § 1961(3).

650. The following pharmacy benefit managers (collectively “PBMs”) are each “persons,” as that term is defined in 18 U.S.C. § 1961(3): (a) **AdvancePCS** (“Advance PCS”), a Delaware corporation with its principal place of business located at 750 West John Carpenter Freeway, Suite 1200, Irving, Texas; Advance PCS is the largest PBM in the United States and currently serves more than 75 million health plan members; (b) **Caremark, Rx, Inc.** (“Caremark Rx”), a Delaware corporation with its principal place of business located at 300 Galloria Tower, Suite 1000, Birmingham, Alabama; Caremark Rx is one of the largest pharmaceutical services companies in the United States with net revenues of approximately \$5.6 billion in 2001; (c) **Express Scripts, Inc.** (“Express Scripts”), a Delaware corporation with its principal place of business located at 13900 Riverpoint Drive, Maryland Heights, Missouri; Express Scripts is the third largest PBM in North America; and (d) **Medco Health Solutions, Inc.** (“Medco Health”), a successor-in-interest to Merck-Medco Managed Care, L.L.C., is a Delaware corporation with its principal place of business located at 100 Parsons Pond Road, Franklin Lakes, New Jersey; since its acquisition in 1993, Medco Health has been a wholly-owned subsidiary of Defendant Drug Manufacturer Merck.

The Manufacturer-PBM RICO Enterprises

651. For purposes of this claim, the RICO “enterprises” are associations-in-fact consisting of (a) one of the PBMs that administered purchases of a Defendant Drug Manufacturer’s brand name drugs and billed its members on the basis of the Defendant Drug Manufacturer’s reported AWPs, and (b) a Defendant Drug Manufacturer, including its directors, employees and agents. These associations-in-fact are collectively referred to herein as the “Manufacturer-PBM Enterprises.”

652. Each of the Manufacturer-PBM Enterprises is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common or shared purposes of selling, purchasing, and administering AWPIDs to individual Plaintiffs and Class members and to participants in those Classes that comprise health and welfare plans, and deriving profits from these activities.

653. Each of the Manufacturer-PBM Enterprises has a systemic linkage because there are contractual relationships, financial ties, and continuing coordination of activities between the Defendant Drug Manufacturer and the specific PBM that are associates. As to each of the Manufacturer-PBM Enterprises, there is a common communication network by which the Defendant Drug Manufacturer and the specific PBM share information on a regular basis. As to each of the Manufacturer-PBM Enterprises, the Defendant Drug Manufacturer and the specific PBM functioned as a continuing unit. At all relevant times, each of the Manufacturer-PBM Enterprises was operated by the specific Defendant Drug Manufacturer for criminal purposes, namely, carrying out the AWP Scheme.

654. Each manufacturer-PBM enterprise had a common purpose of perpetuating use of AWPs as a benchmark for reimbursement in the pharmaceutical industry. The manufacturing defendants had this as a purpose, because without the use of inflated AWPs as an industry price setting benchmark, they would not be able to push the spread to those in the distribution chain.

The PBMs share this common purpose, because they are subject to a great deal of control from the manufacturers. PBMs are now turning to drug manufacturers for hidden profit-making schemes, because PBM clients are no longer allowing PBMs to collect as much for claims administration. Thus, as a result, PBMs have, with the knowing and willful participation and assistance of the drug manufacturers, engaged in hidden profit-making schemes falling into three general categories: (i) garnering rebates and other “soft dollars” from drug manufacturers that the PBM Defendants, to a large extent, keep without disclosing to their health plans the true amounts of the rebates; (ii) pocketing secret spreads between actual drug costs and the prices charged to health plans and their members; and (iii) keeping secret discounts provided by the drug manufacturers in association with the PBMs’ mail order operations.

655. The existence and magnitude of PBM rebates and accompanying profits at the expense of PBM clients is acknowledged within the PBM industry. For example, a recent industry report observed:

[R]ebates paid to the PBMs by pharmaceutical companies continue to increase, as evidenced by the increasing PBM profits . . . [T]his should hold true so long as the PBMs add value [apparently to the drug makers] by moving market share within drug classes.

656. Thus, PBMs were willing participants in the enterprise, and each participant in the enterprise shared many common purposes.

657. Further, as a result of their reliance on the manufacturers, PBMs took instructions and commands from the manufacturers regarding the use of AWP, not only so that they could keep part of the spread, but also so as to continue to earn from the manufacturers: (i) ***Access rebates*** for placement of products on the PBMs’ formulary; (ii) ***Market share rebates*** for garnering higher market share than established targets; (iii) ***Administrative fees*** for assembling data to verify market share results; and (iv) ***Other fees and grants*** in an effort to promote products.

658. In order to garner all of these fees from the drug manufacturers, the PBMs each meet on a frequent basis to discuss drug prices, spreads, marketing opportunities and coordination of all of the above.

659. There is a common communication network between each PBM and each manufacturer for the purpose of implementing the AWP spread scheme and for the exchange of financial rewards for the PBMs activities that benefit the drug company manufacturers.

660. At all relevant times, each one of the PBMs was aware of the Defendants Drug Manufacturers' AWP Scheme, was a knowing and willing participant in that scheme, and reaped profits from that scheme.

661. For purposes of this count, the Manufacturer-PBM Enterprises are identified as follows:

(a) *The Abbott Manufacturer-PBM Enterprises:* The Abbott Manufacturer-PBM Enterprises are four separate associations-in-fact consisting of each of the PBMs that administered purchases of Abbott's AWPIDs and billed its members on the basis of Abbott's reported AWPs, and Abbott, including its directors, employees and agents: (1) the Abbott-AdvancePCS Enterprise; (2) the Abbott-Caremark Rx Enterprise; (3) the Abbott-Express Scripts Enterprise; and (4) the Abbott-Medco Health Enterprise. Each of the Abbott Manufacturer-PBM Enterprises is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common or shared purposes of selling, purchasing, prescribing and administering AWPIDs to Plaintiffs and Class members, and deriving profits from these activities. Each of the Abbott Manufacturer-PBM Enterprises has a systemic linkage because there are contractual relationships, financial ties, and continuing coordination of activities between Abbott and AdvancePCS, Abbott and Caremark Rx, Abbott and Express Scripts, and Abbott and Medco Health. As to each of these Abbott

Manufacturer-PBM Enterprises, there is a common communication network by which Abbott and AdvancePCS, Abbott and Caremark Rx, Abbott and Express Scripts, and Abbott and Medco Health share information on a regular basis. As to each of these Abbott-Manufacturer-PBM Enterprises, Abbott and AdvancePCS, Abbott and Caremark Rx, Abbott and Express Scripts, and Abbott and Medco Health functioned as continuing but separate units. At all relevant times, each of the Abbott Manufacturer-PBM Enterprises was operated and conducted by Abbott for criminal purposes, namely, carrying out the AWP Scheme.

(b) *The Amgen Manufacturer-PBM Enterprises:* The Amgen Manufacturer-PBM Enterprises are four separate associations-in-fact consisting of each of the PBMs that administered purchases of Amgen's AWPIDs and billed its members on the basis of Amgen's reported AWPs, and Amgen, including its directors, employees and agents: (1) the Amgen-AdvancePCS Enterprise; (2) the Amgen-Caremark Rx Enterprise; (3) the Amgen-Express Scripts Enterprise; and (4) the Amgen-Medco Health Enterprise. Each of the Amgen Manufacturer-PBM Enterprises is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common or shared purposes of selling, purchasing, prescribing and administering AWPIDs to Plaintiffs and Class members, and deriving profits from these activities. Each of the Amgen Manufacturer-PBM Enterprises has a systemic linkage because there are contractual relationships, financial ties, and continuing coordination of activities between Amgen and AdvancePCS, Amgen and Caremark Rx, Amgen and Express Scripts, and Amgen and Medco Health. As to each of these Amgen Manufacturer-PBM Enterprises, there is a common communication network by which Amgen and AdvancePCS, Amgen and Caremark Rx, Amgen and Express Scripts, and Amgen and Medco Health share information on a regular basis. As to each of these

Amgen-Manufacturer-PBM Enterprises, Amgen and AdvancePCS, Amgen and Caremark Rx, Amgen and Express Scripts, and Amgen and Medco Health functioned as continuing but separate units. At all relevant times, each of the Amgen Manufacturer-PBM Enterprises was operated and conducted by Amgen for criminal purposes, namely, carrying out the AWP Scheme.

(c) *The AstraZeneca Manufacturer-PBM Enterprises:* The AstraZeneca Manufacturer-PBM Enterprises are four separate associations-in-fact consisting of each of the PBMs that administered purchases of AstraZeneca's AWPIDs and billed its members on the basis of AstraZeneca's reported AWPs, and AstraZeneca, including its directors, employees and agents: (1) the AstraZeneca-AdvancePCS Enterprise; (2) the AstraZeneca-Caremark Rx Enterprise; (3) the AstraZeneca-Express Scripts Enterprise; and (4) the AstraZeneca-Medco Health Enterprise. Each of the AstraZeneca Manufacturer-PBM Enterprises is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common or shared purposes of selling, purchasing, prescribing and administering AWPIDs to Plaintiffs and Class members, and deriving profits from these activities. Each of the AstraZeneca Manufacturer-PBM Enterprises has a systemic linkage because there are contractual relationships, financial ties, and continuing coordination of activities between AstraZeneca and AdvancePCS, AstraZeneca and Caremark Rx, AstraZeneca and Express Scripts, and AstraZeneca and Medco Health. As to each of these AstraZeneca Manufacturer-PBM Enterprises, there is a common communication network by which AstraZeneca and AdvancePCS, AstraZeneca and Caremark Rx, AstraZeneca and Express Scripts, and AstraZeneca and Medco Health share information on a regular basis. As to each of these AstraZeneca-Manufacturer-PBM Enterprises, AstraZeneca and AdvancePCS, AstraZeneca and Caremark Rx, AstraZeneca and Express Scripts, and

AstraZeneca and Medco Health functioned as continuing but separate units. At all relevant times, each of the AstraZeneca Manufacturer-PBM Enterprises was operated and conducted by AstraZeneca for criminal purposes, namely, carrying out the AWP Scheme.

(d) *The Aventis Group Manufacturer-PBM Enterprise:* The Aventis Group Manufacturer-PBM Enterprises are four separate associations-in-fact consisting of each of the PBMs that administered purchases of Aventis Group's AWPIDs and billed its members on the basis of Aventis Group's reported AWPs, and Aventis Group, including its directors, employees and agents: (1) the Aventis Group-AdvancePCS Enterprise; (2) the Aventis Group-Caremark Rx Enterprise; (3) the Aventis Group-Express Scripts Enterprise; and (4) the Aventis Group-Medco Health Enterprise. Each of the Aventis Group Manufacturer-PBM Enterprises is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common or shared purposes of selling, purchasing, prescribing and administering AWPIDs to Plaintiffs and Class members, and deriving profits from these activities. Each of the Aventis Group Manufacturer-PBM Enterprises has a systemic linkage because there are contractual relationships, financial ties, and continuing coordination of activities between Aventis Group and AdvancePCS, Aventis Group and Caremark Rx, Aventis Group and Express Scripts, and Aventis Group and Medco Health. As to each of these Aventis Group Manufacturer-PBM Enterprises, there is a common communication network by which Aventis Group and AdvancePCS, Aventis Group and Caremark Rx, Aventis Group and Express Scripts, and Aventis Group and Medco Health share information on a regular basis. As to each of these Aventis Group-Manufacturer-PBM Enterprises, Aventis Group and AdvancePCS, Aventis Group and Caremark Rx, Aventis Group and Express Scripts, and Aventis Group and Medco Health functioned as continuing but separate units. At all relevant times, each of the Aventis Group

Manufacturer-PBM Enterprises was operated and conducted by Aventis Group for criminal purposes, namely, carrying out the AWP Scheme.

(e) *The Baxter Manufacturer-PBM Enterprises:* The Baxter Manufacturer-PBM Enterprises are four separate associations-in-fact consisting of each of the PBMs that administered purchases of Amgen's AWPIDs and billed its members on the basis of Baxter's reported AWPs, and Baxter, including its directors, employees and agents: (1) the Baxter-AdvancePCS Enterprise; (2) the Baxter-Caremark Rx Enterprise; (3) the Baxter-Express Scripts Enterprise; and (4) the Baxter-Medco Health Enterprise. Each of the Baxter Manufacturer-PBM Enterprises is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common or shared purposes of selling, purchasing, prescribing and administering AWPIDs to Plaintiffs and Class members, and deriving profits from these activities. Each of the Baxter Manufacturer-PBM Enterprises has a systemic linkage because there are contractual relationships, financial ties, and continuing coordination of activities between Baxter and AdvancePCS, Baxter and Caremark Rx, Baxter and Express Scripts, and Baxter and Medco Health. As to each of these Baxter Manufacturer-PBM Enterprises, there is a common communication network by which Baxter and AdvancePCS, Baxter and Caremark Rx, Baxter and Express Scripts, and Baxter and Medco Health share information on a regular basis. As to each of these Baxter Manufacturer-PBM Enterprises, Baxter and AdvancePCS, Baxter and Caremark Rx, Baxter and Express Scripts, and Baxter and Medco Health functioned as continuing but separate units. At all relevant times, each of the Baxter Manufacturer-PBM Enterprises was operated and conducted by Baxter for criminal purposes, namely, carrying out the AWP Scheme.

(f) *The Bayer Manufacturer-PBM Enterprises:* The Bayer Manufacturer-PBM Enterprises are four separate associations-in-fact consisting of each of the PBMs that administered purchases of Bayer's AWPIDs and billed its members on the basis of Bayer's reported AWPs, and Bayer, including its directors, employees and agents: (1) the Bayer-AdvancePCS Enterprise; (2) the Bayer-Caremark Rx Enterprise; (3) the Bayer-Express Scripts Enterprise; and (4) the Bayer-Medco Health Enterprise. Each of the Bayer Manufacturer-PBM Enterprises is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common or shared purposes of selling, purchasing, prescribing and administering AWPIDs to Plaintiffs and Class members, and deriving profits from these activities. Each of the Bayer Manufacturer-PBM Enterprises has a systemic linkage because there are contractual relationships, financial ties, and continuing coordination of activities between Bayer and AdvancePCS, Bayer and Caremark Rx, Bayer and Express Scripts, and Bayer and Medco Health. As to each of these Bayer Manufacturer-PBM Enterprises, there is a common communication network by which Bayer and AdvancePCS, Bayer and Caremark Rx, Bayer and Express Scripts, and Bayer and Medco Health share information on a regular basis. As to each of these Bayer-Manufacturer-PBM Enterprises, Bayer and AdvancePCS, Bayer and Caremark Rx, Bayer and Express Scripts, and Bayer and Medco Health functioned as continuing but separate units. At all relevant times, each of the Bayer Manufacturer-PBM Enterprises was operated and conducted by Bayer for criminal purposes, namely, carrying out the AWP Scheme.

(g) *The Boehringer Group Manufacturer-PBM Enterprise:* The Boehringer Group Manufacturer-PBM Enterprises are four separate associations-in-fact consisting of each of the PBMs that administered purchases of Boehringer Group's AWPIDs and billed its members on the basis of Boehringer Group's reported AWPs, and Boehringer Group,

including its directors, employees and agents: (1) the Boehringer Group-AdvancePCS Enterprise; (2) the Boehringer Group-Caremark Rx Enterprise; (3) the Boehringer Group-Express Scripts Enterprise; and (4) the Boehringer Group-Medco Health Enterprise. Each of the Boehringer Group Manufacturer-PBM Enterprises is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common or shared purposes of selling, purchasing, prescribing and administering AWPIDs to Plaintiffs and Class members, and deriving profits from these activities. Each of the Boehringer Group Manufacturer-PBM Enterprises has a systemic linkage because there are contractual relationships, financial ties, and continuing coordination of activities between Boehringer Group and AdvancePCS, Boehringer Group and Caremark Rx, Boehringer Group and Express Scripts, and Boehringer Group and Medco Health. As to each of these Boehringer Group Manufacturer-PBM Enterprises, there is a common communication network by which Boehringer Group and AdvancePCS, Boehringer Group and Caremark Rx, Boehringer Group and Express Scripts, and Boehringer Group and Medco Health share information on a regular basis. As to each of these Boehringer Group-Manufacturer-PBM Enterprises, Boehringer Group and AdvancePCS, Boehringer Group and Caremark Rx, Boehringer Group and Express Scripts, and Boehringer Group and Medco Health functioned as continuing but separate units. At all relevant times, each of the Boehringer Group Manufacturer-PBM Enterprises was operated and conducted by Boehringer Group for criminal purposes, namely, carrying out the AWP Scheme.

(h) *The Braun Manufacturer-PBM Enterprise:* The Braun Manufacturer-PBM Enterprises are four separate associations-in-fact consisting of each of the PBMs that administered purchases of Braun's AWPIDs and billed its members on the basis of Braun's reported AWPs, and Braun, including its directors, employees and agents: (1)

the Braun-AdvancePCS Enterprise; (2) the Braun-Caremark Rx Enterprise; (3) the Braun-Express Scripts Enterprise; and (4) the Braun-Medco Health Enterprise. Each of the Braun Manufacturer-PBM Enterprises is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common or shared purposes of selling, purchasing, prescribing and administering AWPIDs to Plaintiffs and Class members, and deriving profits from these activities. Each of the Braun Manufacturer-PBM Enterprises has a systemic linkage because there are contractual relationships, financial ties, and continuing coordination of activities between Braun and AdvancePCS, Braun and Caremark Rx, Braun and Express Scripts, and Braun and Medco Health. As to each of these Braun Manufacturer-PBM Enterprises, there is a common communication network by which Braun and AdvancePCS, Braun and Caremark Rx, Braun and Express Scripts, and Braun and Medco Health share information on a regular basis. As to each of these Braun-Manufacturer-PBM Enterprises, Braun and AdvancePCS, Braun and Caremark Rx, Braun and Express Scripts, and Braun and Medco Health functioned as continuing but separate units. At all relevant times, each of the Braun Manufacturer-PBM Enterprises was operated and conducted by Braun for criminal purposes, namely, carrying out the AWP Scheme.

(i) *The BMS Group Manufacturer-PBM Enterprises:* The BMS Group Manufacturer-PBM Enterprises are four separate associations-in-fact consisting of each of the PBMs that administered purchases of BMS Group's AWPIDs and billed its members on the basis of BMS Group's reported AWPs, and BMS Group, including its directors, employees and agents: (1) the BMS Group-AdvancePCS Enterprise; (2) the BMS Group-Caremark Rx Enterprise; (3) the BMS Group-Express Scripts Enterprise; and (4) the BMS Group-Medco Health Enterprise. Each of the BMS Group

Manufacturer-PBM Enterprises is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common or shared purposes of selling, purchasing, prescribing and administering AWPIDs to Plaintiffs and Class members, and deriving profits from these activities. Each of the BMS Group Manufacturer-PBM Enterprises has a systemic linkage because there are contractual relationships, financial ties, and continuing coordination of activities between BMS Group and AdvancePCS, BMS Group and Caremark Rx, BMS Group and Express Scripts, and BMS Group and Medco Health. As to each of these BMS Group Manufacturer-PBM Enterprises, there is a common communication network by which BMS Group and AdvancePCS, BMS Group and Caremark Rx, BMS Group and Express Scripts, and BMS Group and Medco Health share information on a regular basis. As to each of these BMS Group-Manufacturer-PBM Enterprises, BMS Group and AdvancePCS, BMS Group and Caremark Rx, BMS Group and Express Scripts, and BMS Group and Medco Health functioned as continuing but separate units. At all relevant times, each of the BMS Group Manufacturer-PBM Enterprises was operated and conducted by BMS Group for criminal purposes, namely, carrying out the AWP Scheme.

(j) *The Fujisawa Group Manufacturer-PBM Enterprise:* The Fujisawa Group Manufacturer-PBM Enterprises are four separate associations-in-fact consisting of each of the PBMs that administered purchases of Fujisawa Group's AWPIDs and billed its members on the basis of Fujisawa Group's reported AWPs, and Fujisawa Group, including its directors, employees and agents: (1) the Fujisawa Group-AdvancePCS Enterprise; (2) the Fujisawa Group-Caremark Rx Enterprise; (3) the Fujisawa Group-Express Scripts Enterprise; and (4) the Fujisawa Group-Medco Health Enterprise. Each of the Fujisawa Group Manufacturer-PBM Enterprises is an ongoing and continuing business organization consisting of both corporations and individuals that are and have

been associated for the common or shared purposes of selling, purchasing, prescribing and administering AWPIDs to Plaintiffs and Class members, and deriving profits from these activities. Each of the Fujisawa Group Manufacturer-PBM Enterprises has a systemic linkage because there are contractual relationships, financial ties, and continuing coordination of activities between Fujisawa Group and AdvancePCS, Fujisawa Group and Caremark Rx, Fujisawa Group and Express Scripts, and Fujisawa Group and Medco Health. As to each of these Fujisawa Group Manufacturer-PBM Enterprises, there is a common communication network by which Fujisawa Group and AdvancePCS, Fujisawa Group and Caremark Rx, Fujisawa Group and Express Scripts, and Fujisawa Group and Medco Health share information on a regular basis. As to each of these Fujisawa Group-Manufacturer-PBM Enterprises, Fujisawa Group and AdvancePCS, Fujisawa Group and Caremark Rx, Fujisawa Group and Express Scripts, and Fujisawa Group and Medco Health functioned as continuing but separate units. At all relevant times, each of the Fujisawa Group Manufacturer-PBM Enterprises was operated and conducted by Fujisawa Group for criminal purposes, namely, carrying out the AWP Scheme.

(k) *The GSK Group Manufacturer-PBM Enterprises:* The GSK Group Manufacturer-PBM Enterprises are four separate associations-in-fact consisting of each of the PBMs that administered purchases of GSK Group's AWPIDs and billed its members on the basis of GSK Group's reported AWPs, and GSK Group, including its directors, employees and agents: (1) the GSK Group-AdvancePCS Enterprise; (2) the GSK Group-Caremark Rx Enterprise; (3) the GSK Group-Express Scripts Enterprise; and (4) the GSK Group-Medco Health Enterprise. Each of the GSK Group Manufacturer-PBM Enterprises is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common or shared purposes of selling, purchasing, prescribing and administering AWPIDs to Plaintiffs and

Class members, and deriving profits from these activities. Each of the GSK Group Manufacturer-PBM Enterprises has a systemic linkage because there are contractual relationships, financial ties, and continuing coordination of activities between GSK Group and AdvancePCS, GSK Group and Caremark Rx, GSK Group and Express Scripts, and GSK Group and Medco Health. As to each of these GSK Group Manufacturer-PBM Enterprises, there is a common communication network by which GSK Group and AdvancePCS, GSK Group and Caremark Rx, GSK Group and Express Scripts, and GSK Group and Medco Health share information on a regular basis. As to each of these GSK Group-Manufacturer-PBM Enterprises, GSK Group and AdvancePCS, GSK Group and Caremark Rx, GSK Group and Express Scripts, and GSK Group and Medco Health functioned as continuing but separate units. At all relevant times, each of the GSK Group Manufacturer-PBM Enterprises was operated and conducted by GSK Group for criminal purposes, namely, carrying out the AWP Scheme.

(l) *The Hoffman-La Roche Manufacturer-PBM Enterprises:* The Hoffman-La Roche Manufacturer-PBM Enterprises are four separate associations-in-fact consisting of each of the PBMs that administered purchases of Hoffman-La Roche's AWPs, and Hoffman-La Roche, including its directors, employees and agents: (1) the Hoffman-La Roche-AdvancePCS Enterprise; (2) the Hoffman-La Roche-Caremark Rx Enterprise; (3) the Hoffman-La Roche-Express Scripts Enterprise; and (4) the Hoffman-La Roche-Medco Health Enterprise. Each of the Hoffman-La Roche Manufacturer-PBM Enterprises is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common or shared purposes of selling, purchasing, prescribing and administering AWPs to Plaintiffs and Class members, and deriving profits from these activities. Each of the Hoffman-La Roche

Manufacturer-PBM Enterprises has a systemic linkage because there are contractual relationships, financial ties, and continuing coordination of activities between Hoffman-La Roche and AdvancePCS, Hoffman-La Roche and Caremark Rx, Hoffman-La Roche and Express Scripts, and Hoffman-La Roche and Medco Health. As to each of these Hoffman-La Roche Manufacturer-PBM Enterprises, there is a common communication network by which Hoffman-La Roche and AdvancePCS, Hoffman-La Roche and Caremark Rx, Hoffman-La Roche and Express Scripts, and Hoffman-La Roche and Medco Health share information on a regular basis. As to each of these Hoffman-La Roche Manufacturer-PBM Enterprises, Hoffman-La Roche and AdvancePCS, Hoffman-La Roche and Caremark Rx, Hoffman-La Roche and Express Scripts, and Hoffman-La Roche and Medco Health functioned as continuing but separate units. At all relevant times, each of the Hoffman-La Roche Manufacturer-PBM Enterprises was operated and conducted by Hoffman-La Roche for criminal purposes, namely, carrying out the AWP Scheme.

(m) *The Immunex Manufacturer-PBM Enterprises:* The Immunex Manufacturer-PBM Enterprises are four separate associations-in-fact consisting of each of the PBMs that administered purchases of Immunex's AWPIDs and billed its members on the basis of Immunex's reported AWPs, and Immunex, including its directors, employees and agents: (1) the Immunex-AdvancePCS Enterprise; (2) the Immunex-Caremark Rx Enterprise; (3) the Immunex-Express Scripts Enterprise; and (4) the Immunex-Medco Health Enterprise. Each of the Immunex Manufacturer-PBM Enterprises is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common or shared purposes of selling, purchasing, prescribing and administering AWPIDs to Plaintiffs and Class members, and deriving profits from these activities. Each of the Immunex

Manufacturer-PBM Enterprises has a systemic linkage because there are contractual relationships, financial ties, and continuing coordination of activities between Immunex and AdvancePCS, Immunex and Caremark Rx, Immunex and Express Scripts, and Immunex and Medco Health. As to each of these Immunex Manufacturer-PBM Enterprises, there is a common communication network by which Immunex and AdvancePCS, Immunex and Caremark Rx, Immunex and Express Scripts, and Immunex and Medco Health share information on a regular basis. As to each of these Immunex Manufacturer-PBM Enterprises, Immunex and AdvancePCS, Immunex and Caremark Rx, Immunex and Express Scripts, and Immunex and Medco Health functioned as continuing but separate units. At all relevant times, each of the Immunex Manufacturer-PBM Enterprises was operated and conducted by Immunex for criminal purposes, namely, carrying out the AWP Scheme.

(n) *The Johnson & Johnson Group Manufacturer-PBM Enterprise:* The Johnson & Johnson Group Manufacturer-PBM Enterprises are four separate associations-in-fact consisting of each of the PBMs that administered purchases of Johnson & Johnson Group's AWPIDs and billed its members on the basis of Johnson & Johnson Group's reported AWPs, and Johnson & Johnson Group, including its directors, employees and agents: (1) the Johnson & Johnson Group-AdvancePCS Enterprise; (2) the Johnson & Johnson Group-Caremark Rx Enterprise; (3) the Johnson & Johnson Group-Express Scripts Enterprise; and (4) the Johnson & Johnson Group-Medco Health Enterprise. Each of the Johnson & Johnson Group Manufacturer-PBM Enterprises is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common or shared purposes of selling, purchasing, prescribing and administering AWPIDs to Plaintiffs and Class members, and deriving profits from these activities. Each of the Johnson & Johnson Group Manufacturer-PBM

Enterprises has a systemic linkage because there are contractual relationships, financial ties, and continuing coordination of activities between Johnson & Johnson Group and AdvancePCS, Johnson & Johnson Group and Caremark Rx, Johnson & Johnson Group and Express Scripts, and Johnson & Johnson Group and Medco Health. As to each of these Johnson & Johnson Group Manufacturer-PBM Enterprises, there is a common communication network by which Johnson & Johnson Group and AdvancePCS, Johnson & Johnson Group and Caremark Rx, Johnson & Johnson Group and Express Scripts, and Johnson & Johnson Group and Medco Health share information on a regular basis. As to each of these Johnson & Johnson Group-Manufacturer-PBM Enterprises, Johnson & Johnson Group and AdvancePCS, Johnson & Johnson Group and Caremark Rx, Johnson & Johnson Group and Express Scripts, and Johnson & Johnson Group and Medco Health functioned as continuing but separate units. At all relevant times, each of the Johnson & Johnson Group Manufacturer-PBM Enterprises was operated and conducted by Johnson & Johnson Group for criminal purposes, namely, carrying out the AWP Scheme.

(o) *The Pfizer Manufacturer-PBM Enterprises:* The Pfizer Manufacturer-PBM Enterprises are four separate associations-in-fact consisting of each of the PBMs that administered purchases of Pfizer's AWPIDs and billed its members on the basis of Pfizer's reported AWPs, and Pfizer, including its directors, employees and agents: (1) the Pfizer-AdvancePCS Enterprise; (2) the Pfizer-Caremark Rx Enterprise; (3) the Pfizer-Express Scripts Enterprise; and (4) the Pfizer-Medco Health Enterprise. Each of the Pfizer Manufacturer-PBM Enterprises is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common or shared purposes of selling, purchasing, prescribing and administering AWPIDs to Plaintiffs and Class members, and deriving profits from these activities. Each of the Pfizer Manufacturer-PBM Enterprises has a systemic linkage

because there are contractual relationships, financial ties, and continuing coordination of activities between Pfizer and AdvancePCS, Pfizer and Caremark Rx, Pfizer and Express Scripts, and Pfizer and Medco Health. As to each of these Pfizer Manufacturer-PBM Enterprises, there is a common communication network by which Pfizer and AdvancePCS, Pfizer and Caremark Rx, Pfizer and Express Scripts, and Pfizer and Medco Health share information on a regular basis. As to each of these Pfizer Manufacturer-PBM Enterprises, Pfizer and AdvancePCS, Pfizer and Caremark Rx, Pfizer and Express Scripts, and Pfizer and Medco Health functioned as continuing but separate units. At all relevant times, each of the Pfizer Manufacturer-PBM Enterprises was operated and conducted by Pfizer for criminal purposes, namely, carrying out the AWP Scheme.

(p) *The Pharmacia Group Manufacturer-PBM Enterprises:* The Pharmacia Group Manufacturer-PBM Enterprises are four separate associations-in-fact consisting of each of the PBMs that administered purchases of Pharmacia Group's AWPIDs and billed its members on the basis of Pharmacia Group's reported AWPs, and Pharmacia Group, including its directors, employees and agents: (1) the Pharmacia Group-AdvancePCS Enterprise; (2) the Pharmacia Group-Caremark Rx Enterprise; (3) the Pharmacia Group-Express Scripts Enterprise; and (4) the Pharmacia Group-Medco Health Enterprise. Each of the Pharmacia Group Manufacturer-PBM Enterprises is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common or shared purposes of selling, purchasing, prescribing and administering AWPIDs to Plaintiffs and Class members, and deriving profits from these activities. Each of the Pharmacia Group Manufacturer-PBM Enterprises has a systemic linkage because there are contractual relationships, financial ties, and continuing coordination of activities between Pharmacia Group and AdvancePCS, Pharmacia Group and Caremark Rx, Pharmacia Group and Express Scripts, and Pharmacia Group and

Medco Health. As to each of these Pharmacia Group Manufacturer-PBM Enterprises, there is a common communication network by which Pharmacia Group and AdvancePCS, Pharmacia Group and Caremark Rx, Pharmacia Group and Express Scripts, and Pharmacia Group and Medco Health share information on a regular basis. As to each of these Pharmacia Group-Manufacturer-PBM Enterprises, Pharmacia Group and AdvancePCS, Pharmacia Group and Caremark Rx, Pharmacia Group and Express Scripts, and Pharmacia Group and Medco Health functioned as continuing but separate units. At all relevant times, each of the Pharmacia Group Manufacturer-PBM Enterprises was operated and conducted by Pharmacia Group for criminal purposes, namely, carrying out the AWP Scheme.

(q) *The Schering-Plough Group Manufacturer-PBM Enterprises:* The Schering-Plough Group Manufacturer-PBM Enterprises are four separate associations-in-fact consisting of each of the PBMs that administered purchases of Schering-Plough Group's AWPIDs and billed its members on the basis of Schering-Plough Group's reported AWPs, and Schering-Plough Group, including its directors, employees and agents: (1) the Schering-Plough Group-AdvancePCS Enterprise; (2) the Schering-Plough Group-Caremark Rx Enterprise; (3) the Schering-Plough Group-Express Scripts Enterprise; and (4) the Schering-Plough Group-Medco Health Enterprise. Each of the Schering-Plough Group Manufacturer-PBM Enterprises is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common or shared purposes of selling, purchasing, prescribing and administering AWPIDs to Plaintiffs and Class members, and deriving profits from these activities. Each of the Schering-Plough Group Manufacturer-PBM Enterprises has a systemic linkage because there are contractual relationships, financial ties, and continuing coordination of activities between Schering-Plough Group and AdvancePCS,

Schering-Plough Group and Caremark Rx, Schering-Plough Group and Express Scripts, and Schering-Plough Group and Medco Health. As to each of these Schering-Plough Group Manufacturer-PBM Enterprises, there is a common communication network by which Schering-Plough Group and AdvancePCS, Schering-Plough Group and Caremark Rx, Schering-Plough Group and Express Scripts, and Schering-Plough Group and Medco Health share information on a regular basis. As to each of these Schering-Plough Group Manufacturer-PBM Enterprises, Schering-Plough Group and AdvancePCS, Schering-Plough Group and Caremark Rx, Schering-Plough Group and Express Scripts, and Schering-Plough Group and Medco Health functioned as continuing but separate units. At all relevant times, each of the Schering-Plough Group Manufacturer-PBM Enterprises was operated and conducted by Schering-Plough Group for criminal purposes, namely, carrying out the AWP Scheme.

(r) *The Sicor Group Manufacturer-PBM Enterprises:* The Sicor Group Manufacturer-PBM Enterprises are four separate associations-in-fact consisting of each of the PBMs that administered purchases of Sicor Group's AWPIDs and billed its members on the basis of Sicor Group's reported AWPs, and Sicor Group, including its directors, employees and agents: (1) the Sicor Group-AdvancePCS Enterprise; (2) the Sicor Group-Caremark Rx Enterprise; (3) the Sicor Group-Express Scripts Enterprise; and (4) the Sicor Group-Medco Health Enterprise. Each of the Sicor Group Manufacturer-PBM Enterprises is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common or shared purposes of selling, purchasing, prescribing and administering AWPIDs to Plaintiffs and Class members, and deriving profits from these activities. Each of the Sicor Group Manufacturer-PBM Enterprises has a systemic linkage because there are contractual relationships, financial ties, and continuing coordination of activities

between Sicor Group and AdvancePCS, Sicor Group and Caremark Rx, Sicor Group and Express Scripts, and Sicor Group and Medco Health. As to each of these Sicor Group Manufacturer-PBM Enterprises, there is a common communication network by which Sicor Group and AdvancePCS, Sicor Group and Caremark Rx, Sicor Group and Express Scripts, and Sicor Group and Medco Health share information on a regular basis. As to each of these Sicor Group-Manufacturer-PBM Enterprises, Sicor Group and AdvancePCS, Sicor Group and Caremark Rx, Sicor Group and Express Scripts, and Sicor Group and Medco Health functioned as continuing but separate units. At all relevant times, each of the Sicor Group Manufacturer-PBM Enterprises was operated and conducted by Sicor Group for criminal purposes, namely, carrying out the AWP Scheme.

(s) *The Watson Manufacturer-PBM Enterprises:* The Watson Manufacturer-PBM Enterprises are four separate associations-in-fact consisting of each of the PBMs that administered purchases of Watson's AWPs and billed its members on the basis of Watson's reported AWPs, and Pfizer, including its directors, employees and agents: (1) the Watson-AdvancePCS Enterprise; (2) the Watson-Caremark Rx Enterprise; (3) the Watson-Express Scripts Enterprise; and (4) the Watson-Medco Health Enterprise. Each of the Watson Manufacturer-PBM Enterprises is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common or shared purposes of selling, purchasing, prescribing and administering AWPs to Plaintiffs and Class members, and deriving profits from these activities. Each of the Watson Manufacturer-PBM Enterprises has a systemic linkage because there are contractual relationships, financial ties, and continuing coordination of activities between Watson and AdvancePCS, Watson and Caremark Rx, Watson and Express Scripts, and Watson and Medco Health. As to each of these Watson Manufacturer-PBM Enterprises, there is a common communication network by which

Watson and AdvancePCS, Watson and Caremark Rx, Watson and Express Scripts, and Watson and Medco Health share information on a regular basis. As to each of these Watson Manufacturer-PBM Enterprises, Watson and AdvancePCS, Watson and Caremark Rx, Watson and Express Scripts, and Watson and Medco Health functioned as continuing but separate units. At all relevant times, each of the Watson Manufacturer-PBM Enterprises was operated and conducted by Watson for criminal purposes, namely, carrying out the AWP Scheme.

(t) *The TAP Manufacturer-PBM Enterprises:* The TAP Manufacturer-PBM Enterprises are four separate associations-in-fact consisting of each of the PBMs that administered purchases of TAP's AWPIDs and billed its members on the basis of TAP's reported AWPs, and Pfizer, including its directors, employees and agents: (1) the TAP-AdvancePCS Enterprise; (2) the TAP-Caremark Rx Enterprise; (3) the TAP-Express Scripts Enterprise; and (4) the TAP-Medco Health Enterprise. Each of the TAP Manufacturer-PBM Enterprises is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common or shared purposes of selling, purchasing, prescribing and administering AWPIDs to Plaintiffs and Class members, and deriving profits from these activities. Each of the TAP Manufacturer-PBM Enterprises has a systemic linkage because there are contractual relationships, financial ties, and continuing coordination of activities between TAP and AdvancePCS, TAP and Caremark Rx, TAP and Express Scripts, and TAP and Medco Health. As to each of these TAP Manufacturer-PBM Enterprises, there is a common communication network by which TAP and AdvancePCS, TAP and Caremark Rx, TAP and Express Scripts, and TAP and Medco Health share information on a regular basis. As to each of these TAP Manufacturer-PBM Enterprises, TAP and AdvancePCS, TAP and Caremark Rx, TAP and Express Scripts, and TAP and Medco Health functioned

as continuing but separate units. At all relevant times, each of the TAP Manufacturer-PBM Enterprises was operated and conducted by TAP for criminal purposes, namely, carrying out the AWP Scheme.

(u) *The Warrick Manufacturer-PBM Enterprises:* The Warrick Manufacturer-PBM Enterprises are four separate associations-in-fact consisting of each of the PBMs that administered purchases of Warrick's AWPIDs and billed its members on the basis of Warrick's reported AWPs, and Pfizer, including its directors, employees and agents: (1) the Warrick-AdvancePCS Enterprise; (2) the Warrick-Caremark Rx Enterprise; (3) the Warrick-Express Scripts Enterprise; and (4) the Warrick-Medco Health Enterprise. Each of the Warrick Manufacturer-PBM Enterprises is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common or shared purposes of selling, purchasing, prescribing and administering AWPIDs to Plaintiffs and Class members, and deriving profits from these activities. Each of the Warrick Manufacturer-PBM Enterprises has a systemic linkage because there are contractual relationships, financial ties, and continuing coordination of activities between Warrick and AdvancePCS, Warrick and Caremark Rx, Warrick and Express Scripts, and Warrick and Medco Health. As to each of these Warrick Manufacturer-PBM Enterprises, there is a common communication network by which Warrick and AdvancePCS, Warrick and Caremark Rx, Warrick and Express Scripts, and Warrick and Medco Health share information on a regular basis. As to each of these Warrick Manufacturer-PBM Enterprises, Warrick and AdvancePCS, Warrick and Caremark Rx, Warrick and Express Scripts, and Warrick and Medco Health functioned as continuing but separate units. At all relevant times, each of the Warrick Manufacturer-PBM Enterprises was operated and conducted by Warrick for criminal purposes, namely, carrying out the AWP Scheme.

(v) *The Dey Manufacturer-PBM Enterprises:* The Dey Manufacturer-PBM Enterprises are four separate associations-in-fact consisting of each of the PBMs that administered purchases of Dey's AWPIDs and billed its members on the basis of Dey's reported AWPs, and Pfizer, including its directors, employees and agents: (1) the Dey-AdvancePCS Enterprise; (2) the Dey-Caremark Rx Enterprise; (3) the Dey-Express Scripts Enterprise; and (4) the Dey-Medco Health Enterprise. Each of the Dey Manufacturer-PBM Enterprises is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common or shared purposes of selling, purchasing, prescribing and administering AWPIDs to Plaintiffs and Class members, and deriving profits from these activities. Each of the Dey Manufacturer-PBM Enterprises has a systemic linkage because there are contractual relationships, financial ties, and continuing coordination of activities between Dey and AdvancePCS, Dey and Caremark Rx, Dey and Express Scripts, and Dey and Medco Health. As to each of these Dey Manufacturer-PBM Enterprises, there is a common communication network by which Dey and AdvancePCS, Dey and Caremark Rx, Dey and Express Scripts, and Dey and Medco Health share information on a regular basis. As to each of these Dey Manufacturer-PBM Enterprises, Dey and AdvancePCS, Dey and Caremark Rx, Dey and Express Scripts, and Dey and Medco Health functioned as continuing but separate units. At all relevant times, each of the Dey Manufacturer-PBM Enterprises was operated and conducted by Dey for criminal purposes, namely, carrying out the AWP Scheme.

The Defendant Drug Manufacturers' Use of the U.S. Mails and Interstate Wire Facilities

662. Each of the Manufacturer-PBM Enterprises and Medco Health engaged in and affected interstate commerce because they engage in the following activities across state boundaries: The sale, purchase and/or administration of drugs; and/or the transmission and/or

receipt of sales and marketing literature; and/or the transmission to patients of individual prescriptions for drugs by mail-order pharmacies; and/or the transmission and/or receipt of invoices, statements and payments related to the use or administration of drugs. During the Class Period, the Manufacturer-PBM Enterprises and Medco Health participated in the administration of prescription drugs to millions of individuals located throughout the United States.

663. During the Class Period, the Defendants Drug Manufacturers' illegal conduct and wrongful practices were carried out by an array of employees, working across state boundaries, who necessarily relied upon frequent transfers of documents and information, products and funds by the U.S. mails and interstate wire facilities.

664. The nature and pervasiveness of the Defendant Drug Manufacturers' AWP Scheme, which was orchestrated out of the corporate headquarters of the Defendant Drug Manufacturers, necessarily required those headquarters to communicate directly and frequently by the U.S. mails and by interstate wire facilities with the various local district managers overseeing the sales force(s), the numerous pharmaceutical sales representatives who, in turn, directly communicated with providers and employees who communicated with the PBMs, including Medco Health.

665. Many of the precise dates of Defendant Drug Manufacturers' uses of the U.S. mails and interstate wire facilities (and corresponding RICO predicate acts of mail and wire fraud) have been hidden and cannot be alleged without access to these Defendants' books and records. Indeed, an essential part of the successful operation of the AWP Scheme alleged herein depended upon secrecy, and as alleged above, the Defendant Drug Manufacturers took deliberate steps to conceal their wrongdoing. However, Plaintiffs can generally describe the occasions on which the RICO predicate acts of mail fraud and wire fraud occurred, and how those acts were in furtherance of the AWP Scheme and do so below.

666. The Defendant Drug Manufacturers' use of the U.S. mails and interstate wire facilities to perpetrate the AWP Scheme involved thousands of communications throughout the Class Period including, *inter alia*:

- (a) Marketing materials about the AWPs for brand name drugs and the available spread, which were sent by the Defendant Drug Manufacturers to PBMs (including Medco Health) located across the country;
- (b) Written representations of the AWPs made by the Defendant Drug Manufacturers to the Publishers, which were made at least annually and in many cases several times during a single year;
- (c) Thousands of written and oral communications discussing, negotiating and confirming the placement of a Defendant Drug Manufacturer's drugs on a particular PBM's formulary;
- (d) Documents providing information or incentives designed to lessen the prices that each of the PBMs paid for drugs, and/or to conceal those prices or the AWP Scheme;
- (e) Written communications, including checks, relating to rebates, kickbacks or other financial inducements paid to each of the PBMs to persuade them to advocate one Defendant Drug Manufacturers' drug over a drug manufactured by a competitor;
- (f) Written and oral communications with U.S. Government agencies and private insurers that fraudulently misrepresented what the AWPs were, or that were intended to deter investigations into the true nature of the AWPs or to forestall changes to reimbursement based on something other than AWPs;
- (g) Written and oral communications with health insurers and patients;

(h) Receipts of money on tens of thousands of occasions through the U.S. mails and interstate wire facilities – the wrongful proceeds of the Defendant Drug Manufacturers' AWP Scheme; and

(i) In addition to the above-referenced RICO predicate acts, Defendants' corporate headquarters have communicated through use of the U.S. mails and by interstate wire facilities with their various local headquarters or divisions, in furtherance of the AWP Scheme. These mails include some of the documents referenced in this Amended Complaint.

Conduct of the RICO Enterprises' Affairs

667. During the Class Period, each of the Defendant Drug Manufacturers have exerted control over the Manufacturer-PBM Enterprises with which they were associated and, in violation of Section 1962(c) of RICO, each of the Defendant Drug Manufacturers have conducted or participated in the conduct of the affairs of those association-in-fact RICO enterprises, directly or indirectly. Such participation was carried out in the following ways:

- (a) Each of the Defendant Drug Manufacturers has directly controlled the price for its AWPIIDs, which determines the amount of each of the PBMs' compensation;
- (b) Each of the Defendant Drug Manufacturers has directly controlled the AWPs that are reported by the Publishers;
- (d) Each of the Defendant Drug Manufacturers has directly controlled the creation and distribution of marketing, sales, and other materials used to inform each of the PBMs of the profit potential of its AWPIIDs;
- (e) Each of the Defendant Drug Manufacturers has relied upon its employees and agents to promote the AWP Scheme through the U.S. mails, through interstate wire facilities, and through direct contacts with providers and the PBMs; and

(f) Each of the Defendant Drug Manufacturers has controlled and participated in the affairs of the Manufacturer-PBM Enterprises with which they are associated by providing or receiving rebates (as detailed above) or other inducements to place a certain Defendant Drug Manufacturer's AWPs on a PBM formulary or advocate the use of a certain AWP. These inducements include drug manufacturers' payment to PBMs of: (i) access rebates for placement of products on the PBMs' formulary; (ii) market share rebates for garnering higher market share than established targets; (iii) administrative fees for assembling data to verify market share results; and (iv) other fees and grants. Although PBMs typically agree to share rebates in some form with clients, they link the rebates to formulary savings in such a manner that the PBM often is able to secretly retain all of the rebates. Furthermore, PBMs refuse to disclose specific rebate amounts to clients in any fashion other than in the aggregate compared to performance standards, thereby preventing the client from learning the true amount of rebates that the PBM has received in connection with the health plan client.

668. Each of the Manufacturer-PBM Enterprises identified above had a hierarchical decision-making structure headed by the respective Defendant Drug Manufacturer.

669. In violation of Section 1962(c) of RICO, each of the Defendant Drug Manufacturers has conducted the affairs of each of the Manufacturer-PBM Enterprises with which they associated by reporting fraudulently inflated AWPs for AWPs and by submitting false and misleading invoices to Plaintiffs and members of the Classes, thereby inducing Plaintiffs and Class members to pay inflated amounts for AWPs.

The Defendant Drug Manufacturers' Pattern of Racketeering Activity

670. Each of the Defendant Drug Manufacturers has conducted and participated in the affairs of their respective Manufacturer-PBM Enterprises through a pattern of racketeering activity, including acts that are indictable under 18 U.S.C. § 1341, relating to mail fraud, and 18

U.S.C. § 1343, relating to wire fraud. The Defendant Drug Manufacturers' pattern of racketeering likely involved thousands, if not hundreds of thousands, of separate instances of use of the U.S. mails or interstate wire facilities in furtherance of their AWP Scheme. Each of these fraudulent mailings and interstate wire transmissions constitutes a "racketeering activity" within the meaning of 18 U.S.C. § 1961(1) (B). Collectively, these violations constitute a "pattern of racketeering activity," within the meaning of 18 U.S.C. § 1961(5), in which the Defendant Drug Manufacturers intended to defraud Plaintiffs, members of the Classes and other intended victims of the AWP Scheme.

671. The Defendant Drug Manufacturers' fraudulent and unlawful AWP Scheme consisted, in part, of deliberately overstating the AWPs for their AWPIDs, thereby creating a "spread" based on the inflated figure in order to induce each of the PBMs to advocate and favor that particular Defendant Drug Manufacturer's drugs to the members of that PBM's clients. Further, each of the PBMs billed their clients for the particular Defendant Drug Manufacturers' AWPIDs based on the inflated AWPs, which did not reflect the true price paid by the PBMs for the AWPIDs.

672. The AWP Scheme was calculated and intentionally crafted to ensure that Plaintiffs and members of the Classes would be over-billed for AWPIDs. In designing and implementing the AWP Scheme, at all times the Defendant Drug Manufacturers were cognizant of the fact those in the distribution chain that were not part of the enterprise relied upon the integrity of the Defendant Drug Manufacturers in setting the AWPs, as reported by the Publishers.

673. By intentionally and artificially inflating the AWPs, and by subsequently failing to disclose such practices to the individual patients and their insurers, each of the Defendant Drug Manufacturers engaged in a fraudulent and unlawful course of conduct constituting a pattern of racketeering activity.

674. The Defendant Drug Manufacturers' racketeering activities amounted to a common course of conduct, with similar pattern and purpose, intended to deceive Plaintiffs and members of the Classes. Each separate use of the U.S. mails and/or interstate wire facilities employed by each of the Defendant Drug Manufacturers was related, had similar intended purposes, involved similar participants and methods of execution, and had the same results affecting the same victims, including Plaintiffs and members of the Classes. Each of the Defendant Drug Manufacturers has engaged in the pattern of racketeering activity for the purpose of conducting the ongoing business affairs of the respective Manufacturer-PBM Enterprises with which each of them is and was associated-in-fact.

The Defendant Drug Manufacturers' Motive

675. The Defendant Drug Manufacturers' motive in creating and operating the AWP Scheme and conducting the affairs of the Manufacturer-PBM Enterprises described herein was to fraudulently obtain sales of and profits from their AWPIDs.

676. The AWP Scheme was designed to, and did, encourage others, including health care providers, to advocate the use of the Defendant Drug Manufacturers' AWPIDs. Thus, each of the Defendant Drug Manufacturers used the AWP Scheme to sell more of its drugs, thereby fraudulently gaining sales and market share and profits.

Damages Caused by the Defendant Drug Manufacturers' AWP Scheme

677. The Defendant Drug Manufacturers' violations of federal law and their pattern of racketeering activity have directly and proximately caused Plaintiffs and members of the Classes to be injured in their business or property because Plaintiffs and Class members have paid many hundreds of millions of dollars in inflated reimbursements for AWPIDs.

678. The Defendant Drug Manufacturers sent billing statements through the U.S. mails or by interstate wire facilities and reported AWPs and other information by the same methods in

furtherance of their AWP Scheme. Plaintiffs and members of the Classes have made inflated payments for AWPsIDs based on and/or in reliance on reported and false AWPs.

679. Under the provisions of Section 1964(c) of RICO, the Defendant Drug Manufacturers are jointly and severally liable to Plaintiffs and members of the Classes for three times the damages that Plaintiffs and Class members have sustained, plus the costs of bringing this suit, including reasonable attorneys' fees.

COUNT III

DECLARATORY AND OTHER RELIEF PURSUANT TO 28 U.S.C. §§ 2201, 2002

(AGAINST DEFENDANT DRUG MANUFACTURERS FOR UNLAWFUL CONDUCT ASSOCIATED WITH MEDICARE PART B COVERED DRUGS)

680. Plaintiffs, on behalf of themselves and all others similarly situated, reallege and incorporate herein by reference each of the allegations contained in the preceding paragraphs of this Complaint.

681. An actual case and controversy exists between the Plaintiffs and each of the Defendant Drug Manufacturers with respect to the Defendant Drug Manufacturers' conduct of inflating the published reimbursement rates for AWPsIDs. The Plaintiffs contend that setting stated reimbursement prices above the actual average wholesale price for AWPsIDs is unlawful, and that each Defendant Drug Manufacturer does so in violation of applicable law, knowing that Medicare beneficiaries and other end payors will incur similarly inflated co-payments and payments for AWPsIDs.

682. Each Defendant Drug Manufacturer contends to the contrary. Each of the Defendant Drug Manufacturers, either by itself or through groups or its trade association, contend that they may exploit the Medicare reimbursement system without limit, and regardless of its effect on Medicare beneficiaries and their insurers.

683. The Plaintiffs, on behalf of themselves, their constituent members and all others similarly situated, are entitled to a judgment declaring that the practice of the Defendant Drug

Manufacturers of inflating stated reimbursement rates for AWPIDs is unlawful, and are entitled to further relief pursuant to 28 U.S.C. § 2202.

COUNT IV

VIOLATIONS OF CONSUMER PROTECTION STATUTES

684. Plaintiffs, on behalf of themselves and all others similarly situated, reallege and incorporate herein by reference each of the allegations contained in the preceding paragraphs of this Complaint.

685. This Count is asserted by the AWP End Payor Class by each class representative.

686. Defendants are incorporated, or maintain their principal places of business, in either California, Delaware, Illinois, New Jersey, Pennsylvania or Washington. In addition, individual Patient and Third-Party Payor Plaintiffs reside in either California, Florida, New York, Minnesota, Louisiana, Pennsylvania or Texas. Each of these states has enacted statutes to protect consumers against unfair, deceptive or fraudulent business practices, unfair competition and false advertising. The statutes of these states, legally and substantively common, provide consumers with a private right of action, as follows:

<i>California:</i>	Cal. Civ. Code §§ 1750, Bus. & Prof. Code § 17200, <i>et seq.</i> and 17500, <i>et seq.</i>
<i>Delaware:</i>	6 Del. Code §§ 2511-2537
<i>Florida:</i>	Fla. Stat. Stat. §§ 501.201-501.213
<i>Illinois:</i>	815 ILCS § 505/1, <i>et seq.</i>
<i>Louisiana:</i>	La. Rev. Stat. Ann. § 51:1405
<i>Minnesota:</i>	Minn. Stat. Ann. §§ 325D.09 - 325D.16, § 325F.67 - 69
<i>New Jersey:</i>	N.J. Stat. Ann. §§ 56:8-1 - 56:8-24
<i>New York:</i>	N.Y. Gen. Bus. L. §§ 349-350
<i>Pennsylvania:</i>	73 Pa. Stat. § 201-1 <i>et seq.</i>
<i>Texas:</i>	Tex. Bus. & Com. Code §§ 17.41 B 17.63

Washington: RCW 19.86.010, *et seq.*

These statutes do not require a showing of either scienter or individual reliance.

687. Defendants' conduct, as alleged in this Complaint, constitutes unfair and deceptive acts or practices, unconscionable practices, fraud, false pretense, false promise, misrepresentation, concealment, suppression or omission of material fact in violation of these statutes. Defendants' continuing violations include:

- (a) Failing to disclose material facts in the conduct of trade or commerce in that they have not disclosed that the AWP does not reflect the true average wholesale price of the drugs they sell, and that the published AWPs are instead deliberately inflated in order to (1) increase the prices paid by Plaintiffs and the members of the Classes; (2) increase the profitability of the Defendant Drug Manufacturer's drugs to the providers who prescribe or dispense them, and to the other intermediaries that promote them; and thereby (3) increase Defendants' market shares and profits;
- (b) Making false or misleading statements of fact concerning the price of goods in that they have not reported the true AWP paid for their medications in order to accomplish the goals described above;
- (c) Knowingly making false representations in a transaction by representing that the AWP is an accurate reflection of the average wholesale price paid for their drugs when AWP is, in reality, a fictitious and inflated amount;
- (d) Publishing fictitious and inflated AWPs in the *Red Book* and other publications;
- (e) Encouraging Medicare Part B providers to use drugs based upon the "spread" as opposed to medicines being prescribed based on medical reasons; and
- (f) Providing PBMs with a cut on the spread in return for the PBMs' participation in the AWP scheme.

688. Defendants willfully engaged in such practices knowing them to be deceptive and with the intent that Plaintiffs and the Class would rely thereon.

689. The wrongful conduct alleged in this Complaint occurs, and continues to occur, in the ordinary course of Defendants' business or occupation and has caused great harm to Plaintiffs and the Class, who were foreseeable and direct victims.

690. Defendants have injured the public interest, and Defendants' actions continue to pose a threat to the public.

691. As a direct and legal result of Defendants' misleading, deceptive, unfair, false and fraudulent trade practices, Plaintiffs and the Class have sustained damages.

COUNT V

CLAIM FOR INJUNCTIVE RELIEF UNDER SECTION 16 OF THE CLAYTON ACT ARISING FROM THE TOGETHER CARD CONSPIRACY

692. Plaintiffs, on behalf of themselves and the Nationwide End Payor Together Card Class, reallege and incorporate herein by reference each of the allegations contained in the preceding paragraphs of this complaint.

693. The acts of the Together Card Defendants which violated federal and state antitrust laws were authorized, ordered, or done by the Together Card Defendants' officers, agents, employees, or representatives while actively engaged in the management of the Together Card Defendants' business or affairs.

694. Various other individuals, partnerships, sole proprietors, business entities, companies and corporations, presently unknown to Plaintiffs and not named as Together Card Defendants in this complaint, participated as co-conspirators in the violations of federal and state antitrust laws alleged herein and performed acts and made statements in furtherance thereof. Such unknown persons or entities acted as co-conspirators and aided, abetted or participated with the Together Card Defendants in the commission of the wrongful acts alleged in this complaint.

695. During the Class Period, the Together Card Defendants sold, or facilitated the sale of, Together Card Drugs in a continuous and uninterrupted flow of interstate commerce to customers located in countries and states other than the countries or states in which Defendants

produced the Together Card Drugs. The business activities of the Together Card Defendants were thus within the flow of, and substantially affected, interstate trade and commerce.

696. The combination or conspiracy alleged in this Complaint consisted of a continuing agreement, understanding or concert of action by Defendants, and their other co-conspirators, the substantial terms of which were to raise, fix and maintain the AWP spreads of the Together Card Drugs.

697. As the result of the Together Card Defendants' wrongful conduct, Plaintiffs and the Nationwide End Payor Together Card Class paid higher prices for the Together Card Drugs than they would have paid but for the Together Card Defendants' anticompetitive conduct, and have been injured in their business or property.

698. The Together Card Defendants should be enjoined under federal law, including Section 16 of the Clayton Act, from continuing their anticompetitive conduct. Absent an injunction, the effects of this anticompetitive conduct will continue. In a country where tens of thousands of citizens cannot afford prescription drugs, or where the expense of such drugs is a great burden on millions, any continuing anticompetitive conduct is a serious matter that needs injunctive relief as a remedy.

COUNT VI

CLAIM FOR VIOLATION OF SHERMAN ACT, 15 U.S.C. § 1 ON BEHALF OF NATIONWIDE END PAYOR TOGETHER CARD CLASS

699. Plaintiffs, on behalf of themselves and the Nationwide End Payor Together Card Class, reallege and incorporate herein by reference each of the allegations contained in the preceding paragraphs of this complaint.

700. The combination or conspiracy alleged in this complaint consisted of a continuing agreement, understanding or concert of action by the Together Card Defendants, and their other co-conspirators, the substantial terms of which were to raise, fix and maintain the AWP spreads of the Together Card Drugs.

701. The Together Rx Card conspiracy was intended to affect directly, and to affect the end payors of the pharmaceutical products covered by the Together Card program, *i.e.*, the National End Payor Together Card Class and Together Card enrollees. The intent, purpose and effect of the Together Rx Card conspiracy was to cause over-reimbursement for certain drugs, and thereby increase available “spread” dollars for other participants in the distribution channel (*i.e.*, wholesalers, distributors, pharmacies and/or PBMs) to the detriment of the National End Payor Together Card Class.

702. Through the Together Rx Card conspiracy, the Together Card Defendants have in fact caused an increase in end payor reimbursement or payments for many of the drugs that are covered by the Together Rx Card program, and at the same time the conspiracy had the intent, purpose and effect of not affecting (either directly or indirectly) transaction costs and/or prices to all other participants in the distribution chain (*i.e.*, wholesalers, distributors, pharmacies and PBMs).

703. As the result of the Together Card Defendants’ wrongful conduct, Plaintiffs and the Nationwide End Payor Together Card Class paid higher prices for the Together Card Drugs than they would have paid but for Defendants’ anticompetitive conduct, have been injured in their business or property, and have suffered damages in an amount to be determined at trial.

704. Plaintiffs and the Nationwide End Payor Together Card Class are entitled to recover all damages and treble damages allowed under § 1 of the Sherman Act against Together Card Defendants, jointly and severally, together with their costs of suit, including reasonable attorneys’ fees.

COUNT VII

CLAIM FOR VIOLATION OF THE ANTITRUST STATUTES OF THE INDIRECT PURCHASER STATES ON BEHALF OF INDIRECT PURCHASER STATES END PAYOR TOGETHER CARD CLASS

705. Plaintiffs, on behalf of themselves and the Indirect Purchaser States End Payor Together Card Class, reallege and incorporate herein by reference each of the allegations contained in the preceding paragraphs of this complaint. Plaintiffs allege and assert that Plaintiffs and members of the Nationwide End Payor Together Card Class are direct purchasers in that they are the first and only ones in the distribution chain that actually pay and are harmed as a result of the agreement to fix reimbursement rates and the AWP spreads. Everyone else in the distribution chain benefits from the AWP, *i.e.*, they receive a portion of the spread, but they do not pay or reimburse based on AWP. However, to the extent any are deemed indirect purchasers, this Count is asserted alternatively.

706. The Together Card Defendants' conduct described herein constitutes unlawful acts under the antitrust laws of the Indirect Purchaser States as follows:

a. Arizona: The aforementioned practices by the Together Card Defendants

were and are in violation of the Arizona Uniform State Antitrust Act, Ariz. Rev. Stat. §§ 44-1401, *et seq.*, the Arizona Consumer Fraud Act, Ariz. Rev. Stat §§ 44-1521, *et seq.*, and the Constitution of the State of Arizona, Article 14, § 15;

b. California: The aforementioned practices by the Together Card Defendants were and are in violation of the Cartwright Act, Cal. Bus. & Prof. Code §§ 16700, *et seq.* and the California Unfair Competition Act, Cal. Bus. & Prof. Code §§ 17200, *et seq.*;

c. District of Columbia: The aforementioned practices by the Together Card Defendants were and are in violation of the District of Columbia Antitrust Act, D.C. Code §§ 28-4501, *et seq.*;

d. Florida: The aforementioned practices by the Together Card Defendants were and are in violation of the Florida Antitrust Act, Fla. Stat. Ann. §§ 542.15, *et seq.*, and the Florida Deceptive and Unfair Trade Practices Act, Fla. Stat. Ann. §§ 501.201, *et seq.*;

e. Kansas: The aforementioned practices by the Together Card Defendants were and are in violation of the Kansas Monopolies and Unfair Trade Act, Kan. Stat. Ann. §§ 50-101, *et seq.*, and the Kansas Consumer Protection Act, Kan. Stat. Ann §§ 50-623, *et seq.*;

f. Kentucky: The aforementioned practices by the Together Card Defendants were and are in violation of the Kentucky Consumer Protection Act, Ky. Rev. Stat. Ann. §§ 367.110, *et seq.*, and the Kentucky Unfair Trade Practices Act, Ky. Rev. Stat. Ann §§ 365.020, *et seq.*;

g. Louisiana: The aforementioned practices by the Together Card Defendants were and are in violation of the Louisiana Monopolies Law, La. Rev. Stat. Ann. §§ 51:121, *et seq.*, and the Louisiana Unfair Trade Practices and Consumer Protection Law, La. Rev. Stat. Ann. §§ 51:1401, *et seq.*;

h. Maine: The aforementioned practices by the Together Card Defendants were and are in violation of the Maine Monopolies and Profiteering Statute, Me. Rev. Stat. Ann. tit. 10, §§ 1101, *et seq.*, and the Maine Unfair Trade Practices Act, Me. Rev. Stat. Ann. tit. 5, §§ 205-A, *et seq.*;

i. Massachusetts: The aforementioned practices by the Together Card Defendants were and are in violation of the Massachusetts Antitrust Act, Mass. Gen. Laws, ch. 93, and the Massachusetts Consumer Protection Act, Mass. Gen. Laws ch. 93A;

j. Michigan: The aforementioned practices by the Together Card Defendants were and are in violation of the Michigan Antitrust Reform Act, Mich. Comp. Laws §§ 445.771, *et seq.*, and the Michigan Consumer Protection Act, §§ 445.901, *et seq.*;

k. Minnesota: The aforementioned practices by the Together Card

Defendants were and are in violation of the Minnesota Antitrust Law of 1971, Minn. Stat.

§§ 325D.49, *et seq.*, and the Minnesota Consumer Fraud Act, Minn. Stat §§ 325F.67, *et seq.*;

l. Nevada: The aforementioned practices by the Together Card Defendants were and are in violation of the Nevada Unfair Trade Practices Act, Nev. Rev. Stat.

§§ 598A.010, *et seq.*, and the Nevada Deceptive Trade Practices Act, Nev. Rev. Stat.

§§ 598.0903, *et seq.*;

m. New Jersey: The aforementioned practices by the Together Card

Defendants were and are in violation of the New Jersey Antitrust Act, N.J. Stat. Ann. §§ 56:9-1, *et seq.*, and the New Jersey Consumer Fraud Act, N.J. Stat. Ann. §§ 56:8-1, *et seq.*;

n. New Mexico: The aforementioned practices by the Together Card

Defendants were and are in violation of the New Mexico Antitrust Act, N.M. Stat. Ann. §§ 57-1-1, *et seq.*, and the New Mexico Unfair Practices Act, N.M. Stat. Ann. §§ 57-12-1, *et seq.*;

o. New York: The aforementioned practices by the Together Card

Defendants were and are in violation of the Donnelly Act, N.Y. Gen. Bus. Law §§ 340, *et seq.*, and the New York Deceptive Acts and Practices Act, N.Y. Gen. Bus. Law §§ 349, *et seq.*;

p. North Carolina: The aforementioned practices by the Together Card

Defendants were and are in violation of North Carolina's antitrust and unfair competition law, N.C. Gen. Stat. §§ 75-1, *et seq.*;

q. North Dakota: The aforementioned practices by the Together Card

Defendants were and are in violation of the North Dakota Antitrust Act, N.D. Cent. Code §§ 51-08.1-01, *et seq.*, and the North Dakota Consumer Fraud Act, N.D. Cent. Code §§ 51-15-01, *et seq.*;

r. South Dakota: The aforementioned practices of the Together Card

Defendants were and are in violation of South Dakota's antitrust law, S.D. Codified Laws §§ 37-

1-3, *et seq.*, and deceptive trade practices and consumer protection law, S.D. Codified Laws §§ 37-24-1, *et seq.*;

s. Tennessee: The aforementioned practices of the Together Card Defendants were and are in violation the Tennessee Trade Practices Act, Tenn. Code Ann. §§ 47-25-101, *et seq.*, and the Consumer Protection Act, Tenn. Code Ann. §§ 47-18-101, *et seq.*;

t. Vermont: The aforementioned practices of the Together Card Defendants were and are in violation of the Vermont Consumer Fraud Act, Vt. Stat. tit. 9. §§ 2451, *et seq.*;

u. West Virginia: The aforementioned practices by the Together Card Defendants were and are in violation of the West Virginia Antitrust Act, W.Va. Code §§ 47-18-1, *et seq.*, and the West Virginia Consumer Credit and Protection Act, W. Va. Code §§ 46A-6-101, *et seq.*; and

v. Wisconsin: The aforementioned practices by the Together Card Defendants were and are in violation of the Wisconsin Antitrust Act, Wis. Stat. §§ 133.01, *et seq.*, and the Wisconsin Unfair Trade Practices Act, Wis. Stat. §§ 100.20, *et seq.*

707. As the result of the Together Card Defendants' wrongful conduct, Plaintiffs and the Indirect Purchaser States End Payor Together Card Class paid higher prices for the Together Card Drugs than they would have paid but for the Together Card Defendants' anticompetitive conduct, have been injured in their business or property, and have suffered damages in an amount to be determined at trial.

708. Plaintiffs and the Indirect Purchaser States End Payor Together Card Class are entitled to recover all damages and treble damages, as permitted by law under these antitrust statutes against the Together Card Defendants, together with their costs of suit, including reasonable attorneys' fees.

COUNT VIII

VIOLATIONS OF 18 U.S.C. § 1962(C)-(D)

**(AGAINST THE TOGETHER CARD DEFENDANTS
FOR UNLAWFUL CONDUCT ASSOCIATED WITH TOGETHER RX)**

709. Plaintiffs, on behalf of themselves and all others similarly situated, reallege and incorporate herein by reference each of the allegations contained in the preceding paragraphs of this complaint.

710. This Count, which alleges violations of Section 1962(c) and (d) of RICO, 18 U.S.C. § 1962(c)-(d), is asserted against the Together Card Defendants on behalf of the Nationwide End Payor Together Card Class.

711. Plaintiffs, the members of the Nationwide End Payor Together Card Class, and the Together Card Defendants identified in the previous paragraphs of this complaint are each “persons,” as that term is defined in 18 U.S.C. § 1961(3).

712. Together Rx, LLC, which administers the Together Rx Card Program, is the product of an alliance formed by Abbot, AstraZeneca, Aventis, BMS Group, GSK Group, Johnson & Johnson Group, Novartis, and TAP. For purposes of this claim, Together Rx is and was an “enterprise” (the “Together Rx Enterprise”), as that term is defined in 18 U.S.C. § 1961(4). During the Class Period, the Together Card Defendants conducted or participated, directly or indirectly, in the conduct of the affairs of the Together Rx Enterprise through a pattern of racketeering activity and/or conspired to do so, in violation of Section 1962(c) and (d) of RICO, 18 U.S.C. § 1962(c)-(d) (the “Together Rx Card Scheme”).

The Together Card Defendants’ Use of the U.S. Mails and Interstate Wire Facilities

713. The Together Rx Enterprise engaged in and affected interstate commerce because it engaged in the following activities across state boundaries: The dissemination of Together Rx Cards to hundreds of thousands of consumers located nationwide; the use of Together Rx Cards in consumers’ purchases of brand name drugs; the transmission and/or receipt of sales and

marketing literature; the transmission to patients of individual prescriptions for brand name drugs by mail-order pharmacies; and the transmission and/or receipt of invoices, statements and payments related to the use or administration of brand name drugs.

714. During the Together Rx Class Period, the Together Card Defendants' illegal conduct and wrongful practices regarding the Together Rx Card Scheme were carried out by an array of employees, working across state boundaries, who necessarily relied upon frequent transfers of documents and information, products and funds by the U.S. mails and interstate wire facilities.

715. The nature and pervasiveness of the Together Card Defendants' scheme or artifice to defraud consumers via the Together Rx Card Scheme, which was orchestrated out of the corporate headquarters of the Together Card Defendants, necessarily required those headquarters to communicate directly and frequently by the U.S. mails and by interstate wire facilities with each other, with Together Rx, and with consumers located nationwide who signed up for the Together Rx Card Program.

716. Many of the precise dates of Together Card Defendants' uses of the U.S. mails and interstate wire facilities (and corresponding RICO predicate acts of mail and wire fraud) have been hidden and cannot be alleged without access to these Defendants' books and records. Indeed, an essential part of the successful operation of the Together Rx Card Scheme depended upon secrecy, and as alleged above, these defendants took deliberate steps to conceal their wrongdoing. However, Plaintiffs can generally describe the occasions on which the RICO predicate acts of mail fraud and wire fraud occurred, and how those acts were in furtherance of the scheme and do so below.

717. The Together Card Defendants' use of the U.S. mails and interstate wire facilities to perpetrate the Together Rx Card Scheme involved thousands of communications throughout the Class Period including, *inter alia*:

- (a) Joint press releases disseminated by the Together Card Defendants announcing and promoting the Together Rx Card Program;
- (b) Postings on the Internet website of the Together Card Program: www.together-rx.com; and
- (c) Written communications received from consumers located nationwide about the Together Rx Card Program, and the dissemination of written information to such consumers about the Together Rx Card Program.

Conduct of the Together Rx Enterprise's Affairs

718. During the Class Period, each of the Together Card Defendants have exerted control over the Together Rx Enterprise with which they were associated and, in violation of Section 1962(c) of RICO, each of the Together Card Defendants has conducted or participated in the conduct of the affairs of the Together Rx Enterprise, directly or indirectly. During the Class Period, in violation of Section 1962(d) of RICO, 18 U.S.C. § 1962(d), each of the Together Card Defendants has conspired to conduct or participate, directly or indirectly, in the conduct of the affairs of the Together Rx Enterprise. Such participation, direct or indirect, in the affairs of that RICO enterprise was carried out by the Together Card Defendants in the following ways:

- (a) As alleged above, Together Rx represents an alliance of, and was formed by, the Together Card Defendants;
- (b) Each of the Together Card Defendants has participated in designing and drafting the promotional and marketing materials for the Together Rx Card Program including, but not limited to, press releases and Internet website postings;
- (c) Each of the Together Card Defendants has participated in the dissemination of promotional and marketing materials to consumers located nationwide concerning the Together Rx Card Program; and

(d) The sales forces of each of the Together Card Defendants has assisted in distributing promotional and marketing materials concerning the Together Rx Card Program to pharmacies, physicians' offices and community centers located nationwide.

The Together Card Defendants' Pattern of Racketeering Activity

719. Each of the Together Card Defendants have conducted and participated in the affairs of the Together Rx Enterprise through a pattern of racketeering activity, including acts that are indictable under 18 U.S.C. § 1341, relating to mail fraud, and 18 U.S.C. § 1343, relating to wire fraud. The Together Card Defendants' pattern of racketeering likely involved thousands, if not hundreds of thousands, of separate instances of use of the U.S. mails or interstate wire facilities in furtherance of their Together Rx Card Scheme. Each of these fraudulent mailings and interstate wire transmissions constitutes a "racketeering activity" within the meaning of 18 U.S.C. § 1961(1) (B). Collectively, these violations constitute a "pattern of racketeering activity," within the meaning of 18 U.S.C. § 1961(5), in which the Together Card Defendants intended to defraud Plaintiffs, the members of the Nationwide End Payor Together Card Class and other intended victims of the Together Rx Card Scheme.

720. The Together Rx Card Scheme was calculated and intentionally crafted by the Together Card Defendants to ensure that Plaintiffs and members of the Nationwide End Payor Together Card Class would be over-billed (and would overpay) for Together Card drugs. In designing and implementing the Together Rx Card Scheme, at all times the Together Card Defendants were cognizant of the fact that Plaintiffs and members of the Nationwide End Payor Together Card Class rely upon the honesty of the Together Card Defendants in setting the AWPs, as reported by the Publishers.

721. The Together Card Defendants' racketeering activities amounted to a common course of conduct, with similar pattern and purpose, intended to deceive Plaintiffs and members of the Nationwide End Payor Together Card Class. Each separate use of the U.S. mails and/or

interstate wire facilities employed by each of the Together Card Defendants was related, had similar intended purposes, involved similar participants and methods of execution, and had the same results affecting the same victims, including Plaintiffs and members of the Nationwide End Payor Together Card Class. Each of the Together Card Defendants has engaged in the pattern of racketeering activity for the purpose of conducting the ongoing business affairs of the Together Rx Enterprise.

The Together Card Defendants' Motive

722. The Together Card Defendants' motive in creating and operating the Together Rx Card Scheme was to fraudulently obtain sales of and profits from their Together Card Drugs.

723. The Together Rx Card Scheme was designed to, and did, encourage others, including health care providers, to advocate the use of the Together Card Drugs. Thus, each of the Together Card Defendants used the Together Rx Card Scheme to sell more of its drugs, thereby fraudulently gaining sales and market share and profits.

Damages Caused By The Together Card Defendants' Together Rx Card Scheme

724. The violations of federal law and their pattern of racketeering activity have directly and proximately caused Plaintiffs and the members of Nationwide End Payor Together Card Class to be injured in their business or property because Plaintiffs and the members of the Nationwide End Payor Together Card Class have paid millions of dollars in inflated reimbursements or other payments for Together Card Drugs.

725. Under the provisions of Section 1964(c) of RICO, the Together Card Defendants are jointly and severally liable to Plaintiffs and members of the Nationwide End Payor Together Card Class for three times the damages that Plaintiffs and Nationwide End Payor Together Card Class members have sustained, plus the costs of bringing this suit, including reasonable attorneys' fees.

COUNT IX

CIVIL CONSPIRACY

(AGAINST ALL DEFENDANTS IDENTIFIED HEREIN FOR CONSPIRING WITH PBMS)

726. Plaintiffs incorporate the preceding allegations as if fully set forth above.

727. This Court is asserted on behalf of the AWP Payor class by class representative CMHV and the Court has diversity jurisdiction over this claim.

728. Each of the defendants named below, for the purpose of implementing the AWP scheme, and thereby causing plaintiffs and the Class to overpay for AWPIDs, conspired with each of the four major PBMs: AdvancePCS, Caremark, Rx, Inc., Express Scripts, Inc. and Medco Health Solutions. The conspiratorial arrangements are as follows:

(a) *The Abbott Manufacturer-PBM Conspiracies:* The Abbott Manufacturer-PBM Conspiracies are four separate conspiracies consisting of each of the PBMs that administered purchases of Abbott's AWPIDs and billed its members on the basis of Abbott's reported AWPs, and Abbott, including its directors, employees and agents: (1) the Abbott-AdvancePCS; (2) the Abbott-Caremark Rx; (3) the Abbott-Express Scripts; and (4) the Abbott-Medco Health. Each of the Abbott Manufacturer-PBM Conspiracies is an ongoing and continuing conspiracy consisting of both corporations and individuals that are and have been associated for the common or shared purposes of selling, purchasing, prescribing and administering AWPIDs to individual Plaintiffs and Class members.

(b) *The Amgen Manufacturer-PBM Conspiracies:* The Amgen Manufacturer-PBM Conspiracies are four separate associations-in-fact consisting of each of the PBMs that administered purchases of Amgen's AWPIDs and billed its members on the basis of Amgen's reported AWPs, and Amgen, including its directors, employees and agents: (1) the Amgen-AdvancePCS; (2) the Amgen-Caremark Rx; (3) the Amgen-Express Scripts;

and (4) the Amgen-Medco Health. Each of the Amgen Manufacturer-PBM Conspiracies is an ongoing and continuing conspiracy consisting of both corporations and individuals that are and have been associated for the common or shared purposes of selling, purchasing, prescribing and administering AWPIDs drugs to individual Plaintiffs and Class members.

(c) *The AstraZeneca Manufacturer-PBM Conspiracies:* The AstraZeneca Manufacturer-PBM Conspiracies are four separate conspiracies consisting of each of the PBMs that administered purchases of AstraZeneca's AWPIDs and billed its members on the basis of AstraZeneca's reported AWPs, and AstraZeneca, including its directors, employees and agents: (1) the AstraZeneca-AdvancePCS; (2) the AstraZeneca-Caremark Rx; (3) the AstraZeneca-Express Scripts; and (4) the AstraZeneca-Medco Health. Each of the AstraZeneca Manufacturer-PBM Conspiracies is an ongoing and continuing conspiracy consisting of both corporations and individuals that are and have been associated for the common or shared purposes of selling, purchasing, prescribing and administering AWPIDs to individual Plaintiffs and Class members.

(d) *The Aventis Group Manufacturer-PBM Conspiracies:* The Aventis Group Manufacturer-PBM Conspiracies are four separate associations-in-fact consisting of each of the PBMs that administered purchases of Aventis Group's AWPIDs and billed its members on the basis of Aventis Group's reported AWPs, and Aventis Group, including its directors, employees and agents: (1) the Aventis Group-AdvancePCS; (2) the Aventis Group-Caremark Rx; (3) the Aventis Group-Express Scripts; and (4) the Aventis Group-Medco Health. Each of the Aventis Group Manufacturer-PBM Conspiracies is an ongoing and continuing conspiracy consisting of both corporations and individuals that are and have been associated for the common or shared purposes of selling, purchasing, prescribing and administering AWPIDs to individual Plaintiffs and Class members.

(e) *The Baxter Manufacturer-PBM Conspiracies:* The Baxter Manufacturer-PBM Conspiracies are four separate conspiracies consisting of each of the PBMs that administered purchases of Baxter's AWPIDs and billed its members on the basis of Baxter's reported AWPs, and Baxter, including its directors, employees and agents: (1) the Baxter-AdvancePCS; (2) the Baxter-Caremark Rx; (3) the Baxter-Express Scripts; and (4) the Baxter-Medco Health. Each of the Baxter Manufacturer-PBM Conspiracies is an ongoing and continuing conspiracy organization consisting of both corporations and individuals that are and have been associated for the common or shared purposes of selling, purchasing, prescribing and administering AWPIDs to individual Plaintiffs and Class members.

(f) *The Bayer Manufacturer-PBM Conspiracies:* The Bayer Manufacturer-PBM Conspiracy are four separate conspiracies consisting of each of the PBMs that administered purchases of Bayer's AWPIDs and billed its members on the basis of Bayer's reported AWPs, and Bayer, including its directors, employees and agents: (1) the Bayer-AdvancePCS; (2) the Bayer-Caremark Rx; (3) the Bayer-Express Scripts; and (4) the Bayer-Medco Health. Each of the Bayer Manufacturer-PBM Conspiracies is an ongoing and continuing conspiracy consisting of both corporations and individuals that are and have been associated for the common or shared purposes of selling, purchasing, prescribing and administering AWPIDs to individual Plaintiffs and Class members.

(g) *The BMS Group Manufacturer-PBM Conspiracies:* The BMS Group Manufacturer-PBM Conspiracies are four separate conspiracies consisting of each of the PBMs that administered purchases of BMS Group's AWPIDs and billed its members on the basis of BMS Group's reported AWPs, and BMS Group, including its directors, employees and agents: (1) the BMS Group-AdvancePCS; (2) the BMS Group-Caremark

Rx; (3) the BMS Group-Express Scripts; and (4) the BMS Group-Medco Health. Each of the BMS Group Manufacturer-PBM Conspiracies is an ongoing and continuing conspiracy consisting of both corporations and individuals that are and have been associated for the common or shared purposes of selling, purchasing, prescribing and administering AWPIDs to individual Plaintiffs and Class members.

(h) *The GSK Group Manufacturer-PBM Conspiracies:* The GSK Group Manufacturer-PBM Conspiracies are four separate conspiracies consisting of each of the PBMs that administered purchases of GSK Group's AWPIDs and billed its members on the basis of GSK Group's reported AWPs, and GSK Group, including its directors, employees and agents: (1) the GSK Group-AdvancePCS; (2) the GSK Group-Caremark Rx; (3) the GSK Group-Express Scripts; and (4) the GSK Group-Medco Health. Each of the GSK Group Manufacturer-PBM Conspiracies is an ongoing and continuing conspiracy consisting of both corporations and individuals that are and have been associated for the common or shared purposes of selling, purchasing, prescribing and administering AWPIDs to individual Plaintiffs and Class members.

(i) *The Hoffman-La Roche Manufacturer-PBM Conspiracies:* The Hoffman-La Roche Manufacturer-PBM Conspiracies are four separate conspiracies consisting of each of the PBMs that administered purchases of Hoffman-La Roche's AWPIDs and billed its members on the basis of Hoffman-La Roche's reported AWPs, and Hoffman-La Roche, including its directors, employees and agents: (1) the Hoffman-La Roche-AdvancePCS; (2) the Hoffman-La Roche-Caremark Rx; (3) the Hoffman-La Roche-Express Scripts; and (4) the Hoffman-La Roche-Medco Health. Each of the Hoffman-La Roche Manufacturer-PBM Conspiracies is an ongoing and continuing conspiracy consisting of both corporations and individuals that are and have been associated for the

common or shared purposes of selling, purchasing, prescribing and administering AWPIDs to individual Plaintiffs and Class members.

(j) *The Immunex Manufacturer-PBM Enterprises:* The Immunex Manufacturer-PBM Conspiracies are four separate conspiracies consisting of each of the PBMs that administered purchases of Immunex's AWPIDs and billed its members on the basis of Immunex's reported AWPs, and Immunex, including its directors, employees and agents: (1) the Immunex-AdvancePCS; (2) the Immunex-Caremark Rx; (3) the Immunex-Express Scripts; and (4) the Immunex-Medco Health. Each of the Immunex Manufacturer-PBM Conspiracies is an ongoing and continuing conspiracy consisting of both corporations and individuals that are and have been associated for the common or shared purposes of selling, purchasing, prescribing and administering AWPIDs to individual Plaintiffs and Class members.

(k) *The Johnson & Johnson Group Manufacturer-PBM Conspiracies:* The Johnson & Johnson Group Manufacturer-PBM Conspiracies are four separate conspiracies consisting of each of the PBMs that administered purchases of Johnson & Johnson Group's AWPIDs and billed its members on the basis of Johnson & Johnson Group's reported AWPs, and Johnson & Johnson Group, including its directors, employees and agents: (1) the Johnson & Johnson Group-AdvancePCS; (2) the Johnson & Johnson Group-Caremark Rx; (3) the Johnson & Johnson Group-Express Scripts; and (4) the Johnson & Johnson Group-Medco Health. Each of the Johnson & Johnson Group Manufacturer-PBM Conspiracies is an ongoing and continuing conspiracy consisting of both corporations and individuals that are and have been associated for the common or shared purposes of selling, purchasing, prescribing and administering AWPIDs to individual Plaintiffs and Class members.

(l) *The Pfizer Manufacturer-PBM Conspiracies:* The Pfizer Manufacturer-PBM Conspiracies are four separate conspiracies consisting of each of the PBMs that administered purchases of Pfizer's AWPIDs and billed its members on the basis of Pfizer's reported AWPs, and Pfizer, including its directors, employees and agents: (1) the Pfizer-AdvancePCS; (2) the Pfizer-Caremark Rx; (3) the Pfizer-Express Scripts; and (4) the Pfizer-Medco Health. Each of the Pfizer Manufacturer-PBM Conspiracies is an ongoing and continuing conspiracy consisting of both corporations and individuals that are and have been associated for the common or shared purposes of selling, purchasing, prescribing and administering AWPIDs to individual Plaintiffs and Class members.

(m) *The Pharmacia Group Manufacturer-PBM Conspiracies:* The Pharmacia Group Manufacturer-PBM Conspiracies are four separate conspiracies consisting of each of the PBMs that administered purchases of Pharmacia Group's AWPIDs and billed its members on the basis of Pharmacia Group's reported AWPs, and Pharmacia Group, including its directors, employees and agents: (1) the Pharmacia Group-AdvancePCS; (2) the Pharmacia Group-Caremark Rx; (3) the Pharmacia Group-Express Scripts; and (4) the Pharmacia Group-Medco Health. Each of the Pharmacia Group Manufacturer-PBM Conspiracies is an ongoing and continuing conspiracy consisting of both corporations and individuals that are and have been associated for the common or shared purposes of selling, purchasing, prescribing and administering AWPIDs to individual Plaintiffs and Class members.

(n) *The Schering-Plough Group Manufacturer-PBM Conspiracies:* The Schering-Plough Group Manufacturer-PBM Conspiracies are four separate conspiracies consisting of each of the PBMs that administered purchases of Schering-Plough Group's AWPIDs and billed its members on the basis of Schering-Plough Group's reported

AWPs, and Schering-Plough Group, including its directors, employees and agents:

(1) the Schering-Plough Group-AdvancePCS; (2) the Schering-Plough Group-Caremark Rx; (3) the Schering-Plough Group-Express Scripts; and (4) the Schering-Plough Group-Medco Health. Each of the Schering-Plough Group Manufacturer-PBM Conspiracies is an ongoing and continuing conspiracy consisting of both corporations and individuals that are and have been associated for the common or shared purposes of selling, purchasing, prescribing and administering AWPIDs to individual Plaintiffs and Class members.

(o) *The Sicor Group Manufacturer-PBM Conspiracies:* The Sicor Group Manufacturer-PBM Conspiracies are four separate conspiracies consisting of each of the PBMs that administered purchases of Sicor Group's AWPIDs and billed its members on the basis of Sicor Group's reported AWPs, and Sicor Group, including its directors, employees and agents: (1) the Sicor Group-AdvancePCS; (2) the Sicor Group-Caremark Rx; (3) the Sicor Group-Express Scripts; and (4) the Sicor Group-Medco Health. Each of the Sicor Group Manufacturer-PBM Conspiracies is an ongoing and continuing conspiracy consisting of both corporations and individuals that are and have been associated for the common or shared purposes of selling, purchasing, prescribing and administering AWPIDs to individual Plaintiffs and Class members.

(p) *The TAP Group Manufacturer-PBM Conspiracies:* The TAP Group Manufacturer-PBM Conspiracies are four separate conspiracies consisting of each of the PBMs that administered purchases of The TAP Group's AWPIDs and billed its members on the basis of The TAP Group's reported AWPs, and Pfizer, including its directors, employees and agents: (1) The TAP Group-AdvancePCS; (2) The TAP Group-Caremark Rx; (3) The TAP Group-Express Scripts; and (4) The TAP Group-Medco Health. Each of The TAP Group Manufacturer-PBM Conspiracies is an ongoing and continuing

conspiracy consisting of both corporations and individuals that are and have been associated for the common or shared purposes of selling, purchasing, prescribing and administering AWPIDs to individual Plaintiffs and Class members.

(q) *The Watson Manufacturer-PBM Conspiracies:* The Watson Manufacturer-PBM Conspiracies are four separate conspiracies consisting of each of the PBMs that administered purchases of Watson's AWPIDs and billed its members on the basis of Watson's reported AWPs, and Pfizer, including its directors, employees and agents: (1) the Watson-AdvancePCS; (2) the Watson-Caremark Rx; (3) the Watson-Express Scripts; and (4) the Watson-Medco Health. Each of the Watson Manufacturer-PBM Conspiracies is an ongoing and continuing conspiracy consisting of both corporations and individuals that are and have been associated for the common or shared purposes of selling, purchasing, prescribing and administering AWPIDs to individual Plaintiffs and Class members.

(r) *The Warrick Manufacturer – PBM Conspiracies:* The Warrick Manufacturer-PBM Conspiracies are four separate conspiracies consisting of each of the PBMs that administered purchases of Warrick's AWPIDs and billed its members on the basis of Warrick's reported AWPs, and Pfizer, including its directors, employees and agents: (1) Warrick-AdvancePCS; (2) Warrick-Caremark Rx; (3) Warrick-Express Scripts; and (4) Warrick-Medco Health. Each of the Warrick Manufacturer-PBM Conspiracies is an ongoing and continuing conspiracy consisting of both corporations and individuals that are and have been associated for the common or shared purposes of selling, purchasing, prescribing and administering AWPIDs to individual Plaintiffs and Class members.

(s) *The Dey-PBM Conspiracies:* The Dey-PBM Conspiracies are four separate conspiracies consisting of each of the PBMs that administered purchases of

Dey's AWPIDs and billed its members on the basis of Dey's reported AWPs, and Pfizer, including its directors, employees and agents: (1) Dey -AdvancePCS; (2) Dey-Caremark Rx; (3) Dey -Express Scripts; and (4) Dey -Medco Health. Each of Dey-PBM Conspiracies is an ongoing and continuing conspiracy consisting of both corporations and individuals that are and have been associated for the common or shared purposes of selling, purchasing, prescribing and administering AWPIDs to individual Plaintiffs and Class members.

(t) *The Boehringer Group-PBM Conspiracies:* The Boehringer Group-PBM Conspiracies are four separate conspiracies consisting of each of the PBMs that administered purchases of Boehringer Group's AWPIDs and billed its members on the basis of Boehringer Group's reported AWPs, and Pfizer, including its directors, employees and agents: (1) Boehringer Group-AdvancePCS; (2) Boehringer Group-Caremark Rx; (3) Boehringer Group-Express Scripts; and (4) Boehringer Group-Medco Health. Each of Boehringer Group-PBM Conspiracies is an ongoing and continuing conspiracy consisting of both corporations and individuals that are and have been associated for the common or shared purposes of selling, purchasing, prescribing and administering AWPIDs to individual Plaintiffs and Class members.

(u) *The B. Braun-PBM Conspiracies:* The B. Braun-PBM Conspiracies are four separate conspiracies consisting of each of the PBMs that administered purchases of B. Braun's AWPIDs and billed its members on the basis of B. Braun's reported AWPs, and Pfizer, including its directors, employees and agents: (1) B. Braun-AdvancePCS; (2) B. Braun-Caremark Rx; (3) B. Braun-Express Scripts; and (4) B. Braun-Medco Health. Each of B. Braun-PBM Conspiracies is an ongoing and continuing conspiracy consisting of both corporations and individuals that are and have been associated for the

common or shared purposes of selling, purchasing, prescribing and administering AWPIDs to individual Plaintiffs and Class members.

(v) *The Fujisawa-PBM Conspiracies:* The Fujisawa-PBM Conspiracies are four separate conspiracies consisting of each of the PBMs that administered purchases of Fujisawa's AWPIDs and billed its members on the basis of Fujisawa's reported AWPs, and Pfizer, including its directors, employees and agents: (1) Fujisawa-AdvancePCS; (2) Fujisawa-Caremark Rx; (3) Fujisawa-Express Scripts; and (4) Fujisawa-Medco Health. Each of Fujisawa-PBM Conspiracies is an ongoing and continuing conspiracy consisting of both corporations and individuals that are and have been associated for the common or shared purposes of selling, purchasing, prescribing and administering AWPIDs to individual Plaintiffs and Class members.

729. Defendants consciously conspired and deliberately pursued a common plan or design to commit tortious acts, with each PBM that was part of its conspiracy, subjecting each to joint liability. Each Defendant Drug Manufacturer and each PBM had the common purpose of perpetuating a reimbursement system based on AWP, because such a system financially benefits **both** the manufacturer and the PBM. The Defendant Drug Manufacturers deliberately and fraudulently overstate the AWPs for their AWPIDs, thereby creating a "spread" based on the inflated figure in order to obtain each of the PBM agreement to advocate and favor that particular Defendant Drug Manufacturer's drugs to the members of that PBM's clients. Each of the PBMs then billed their clients for the particular Defendant Drug Manufacturers' AWPIDs based on the inflated AWPs, which did not reflect the true price paid by the PBMs for the AWPIDs. All of these acts – and more – were done as part of a conspiracy to deceive payors, in violation of applicable state consumer protection laws and the common law of fraud. All of these acts were done in violation of Medicare anti-fraud kickback statutes and were done pursuant to acts of wire and mail fraud.

730. Defendants each committed an unlawful act or acts in furtherance of this conspiracy, including:

- (a) Issuing false marketing materials about the AWPs for AWPIDs and the available spread, which were sent by the Defendant Drug Manufacturers to PBMs (including Medco Health) located across the country;
- (b) Written representations of the AWPs made by the Defendant Drug Manufacturers to the Publishers, which were made at least annually and in many cases several times during a single year and which the PBMs knew were false;
- (c) Thousands of written and oral communications discussing, negotiating and confirming the placement of a Defendant Drug Manufacturer's brand name drugs on a particular PBM's formulary;
- (d) Documents providing information or incentives designed to lessen the prices that each of the PBMs paid for AWPIDs, and/or to conceal those prices or the AWP Scheme;
- (e) Written communications, including checks, relating to rebates, kickbacks or other financial inducements paid to each of the PBMs to persuade them to advocate one Defendant Drug Manufacturers' AWPIDs over a drug manufactured by a competitor;
- (f) Written and oral communications with U.S. Government agencies and private insurers that fraudulently misrepresented what the AWPs were, or that were intended to deter investigations into the true nature of the AWPs or to forestall changes to reimbursement based on something other than AWPs;
- (g) Written and oral communications with health insurers and patients, including Plaintiffs and the members of Classes, inducing payments for the drugs that were made in reliance on AWPs; and

(h) Receipts of money on tens of thousands of occasions through the U.S. mails and interstate wire facilities – the wrongful proceeds of the Defendant Drug Manufacturers' AWP Scheme.

731. All of these acts were done as part of a conspiracy to deceive end payors, in violation of applicable state consumer protection laws and the common law of fraud. All of these acts were also committed in violation of applicable Medicare anti-fraud kickback statutes, and were committed pursuant to acts of unlawful instances of mail and wire fraud.

732. Plaintiffs are entitled to a presumption of reliance on the false representations, concealments and nondisclosures by Defendants. The Class Members were ignorant of Defendants' representations and were ignorant of the full and true facts suppressed by Defendants, and such reliance was justified.

733. As a direct, proximate result of this conspiracy, Plaintiffs and Class Members have been injured, as they have suffered and continue to suffer economic losses and general and specific damages, all in an amount to be determined according to proof.

COUNT X

CIVIL CONSPIRACY

(AGAINST THE TOGETHER CARD DEFENDANTS)

734. Plaintiffs incorporate the preceding allegations as if fully set forth above.

735. This count is asserted by the Nationwide End Payor Together Card Class, and by class representative CMHV. The Court has diversity jurisdiction over this claim.

736. Each of the Together Card Defendants joined in a conspiracy to fix, set and/or maintain the spread between their reported AWP and WAC and each agreed to raise their AWPs prior to implementation of the Together Card Program. Each Together Card Defendant also agreed to publish AWPs that were inflated. Each Together Card Defendant also knew that the

other Together Card Defendant's AWPs were often inflated, so each was aware that by agreeing to raise and fix AWPs, they were perpetuating the use of inflated AWPs on a nationwide basis.

737. The Together Card Defendants consciously conspired and deliberately pursued a common plan or design to commit tortious acts, subjecting each to joint liability.

738. Together Card Defendants each committed unlawful act or acts in furtherance of this conspiracy, including acts violating the Sherman Act, state consumer protection laws, the common law and committed acts of mail and wire fraud. All of these acts were in furtherance of the conspiracy.

739. As a necessary, inevitable and intended part of the conspiracy (and as detailed throughout this complaint), each of the Together Card Defendants structured, arranged and/or otherwise participated in transactions designed to conceal the scheme.

740. Plaintiffs are entitled to a presumption of reliance on the false representations, concealments and nondisclosures by the Together Card Defendants. The Nationwide End Payor Together Card Class Members were ignorant of Together Card Defendants' conduct and were ignorant of the full and true facts suppressed by them, and such reliance was justified.

741. As a direct, proximate result of this conspiracy, Plaintiffs and the Nationwide End Payor Together Card Class Members have been injured, as they have suffered and continue to suffer economic losses and general and specific damages, all in an amount to be determined according to proof.

X. PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray that:

A. The Court determine that this action may be maintained as a class action pursuant to Rule 23(b) (2) of the Federal Rules of Civil Procedure with respect to Plaintiffs' claims for declaratory, equitable and injunctive relief, and Rule 23(b) (3) of the Federal Rules of Civil

Procedure with respect to the claims for damages, and declaring Plaintiffs as representatives of the Classes and their counsel as counsel for the Classes;

- B. The conduct alleged herein be declared, adjudged and decreed to be unlawful;
- C. Plaintiffs and the Classes be granted an award of damages in such amount to be determined at trial, with trebling under Counts I, II, VI and VIII;
- D. Plaintiffs and the Classes be granted an award of punitive damages in such amount to be determined at trial;
- E. Defendants be enjoined from continuing the illegal activities alleged herein;
- F. Plaintiffs and the Classes recover their costs of suit, including reasonable attorneys' fees and expenses as provided by law; and
- G. Plaintiffs and the Classes be granted such other, further, and different relief as the nature of the case may require or as may be determined to be just, equitable, and proper by this Court.

XI. DEMAND FOR JURY TRIAL

Plaintiffs demand a jury trial on all issues so triable.

DATED: December 5, 2003.

Boston, Massachusetts

By Steve W. Berman/Signature on File

Thomas M. Sobol
Edward Notargiacomo
Hagens Berman LLP
225 Franklin Street, 26th Floor
Boston, MA 02110
Telephone: (617) 482-3700
Facsimile: (617) 482-3003

Steve W. Berman
Sean R. Matt
Hagens Berman LLP
1301 Fifth Avenue, Suite 2900
Seattle, WA 98101
Telephone: (206) 623-7292
Facsimile: (206) 623-0594

LIAISON AND CO-LEAD COUNSEL

Eugene A. Spector
Jeffrey Kodroff
Spector, Roseman & Kodroff, P.C.
1818 Market Street, Suite 2500
Philadelphia, PA 19103
Telephone: (215) 496-0300
Facsimile: (215) 496-6611

Marc H. Edelson
Hoffman & Edelson
45 West Court Street
Doylestown, PA 18901
Telephone: (215) 230-8043
Facsimile: (215) 230-8735

Kenneth A. Wexler
Elizabeth Fegan Hartweg
The Wexler Firm
One North LaSalle Street, Suite 2000
Chicago, IL 60602
Telephone: (312) 346-2222
Facsimile: (312) 346-0022

Samuel Heins
Brian Williams
Heins, Mills & Olson, P.C.
700 Northstar East
608 Second Avenue South
Minneapolis, MN 55402
Telephone: (612) 338-4605
Facsimile: (612) 338-4692

CO-LEAD COUNSEL

Michael McShane
Alexander, Hawes & Audet, LLP
300 Montgomery Street, Suite 400
San Francisco, CA 94104
Telephone: (415) 982-1886
Facsimile: (415) 576-1776

Robert E. Piper, Jr.
Piper & Associates
624 Pierre Avenue
Shreveport, LA 71103
Telephone: (318) 226-0826
Facsimile: (318) 424-9900

PLAINTIFFS LEAD COUNSEL COMMITTEE

Anthony Bolognese
Bolognese & Associates
One Penn Center
1617 JFK Boulevard, Suite 650
Philadelphia, PA 19103
Tel: (215) 814-6750
Fax: (215) 814-6764

Jonathan W. Cuneo
The Cuneo Law Group
317 Massachusetts Ave. N.E., Suite 300
Washington, DC 20002
Tel: (202) 789-3960
Fax: (202) 789-1813

Neal Goldstein (Of Counsel)
Freedman & Lorry, PC
400 Market Street, Suit 900
Philadelphia, PA 19106
Tel: (215) 925-8400
Fax: (215) 925-7516

Michael E. Criden
Hanzman & Criden, PA
Commerce Bank Center, Suite 400
220 Alhambra Circle
Coral Gables, FL 33134
Tel: (305) 357-9000
Fax: (305) 357-9050

Blake M. Harper
Kirk B. Hulett
Hulett Harper LLP
550 West C Street, Suite 1700
San Diego, CA 92101
Tel: (619) 338-1133
Fax: (619) 338-1139

Jonathan D. Karmel
Karmel & Gilden
221 N. LaSalle Street
Suite 1414
Chicago, IL 60601
Tel: (312) 641-2910
Fax: (312) 641-0781

Dianne M. Nast
Roda & Nast, PC
801 Estelle Drive
Lancaster, PA 17601
Tel: 717-892-3000
Fax: 717-892-1200

Henry H. Rossbacher
Rossbacher & Associates
811 Wilshire Boulevard, Suite 1650
Los Angeles, CA 90017-2666
Tel: (213) 895-6500
Fax: (213) 895-6161

Jonathan Shub
Sheller, Ludwig & Badey, P.C.
1528 Walnut Street, 3rd Floor
Philadelphia, PA 19102
Tel: (215) 790-7300
Fax: (215) 546-0942

Scott R. Shepherd
Shepherd & Finkleman, LLC
117 Gayley Street, Suite 200
Media, PA 19063
Tel: (610) 891-9880
Fax: (610) 891-9883

Lisa J. Rodriguez
Ira Neil Richards
Trujillo Rodriguez& Richards, LLC
The Penthouse
226 West Rittenhouse Square
Philadelphia, PA 19103
Tel: (215) 731-9004
Fax: (215) 731-9044

Mitchell A. Toups
Weller, Green, Toups & Terrell, L.L.P.
2615 Calder Street, Suite 400
Beaumont, TX 77704
Tel: (409) 838-0101
Fax: 409-838-6780

Damon Young
Lance Lee
Young, Pickett & Lee
4122 Texas Boulevard
Texarkana, AR/TX 75504
Tel: (903) 794-1303
Fax: 903-792-5098; 903-794-5098

Stephen C. Richman, Esq.
Markowitz & Richman
121 South Broad Street
1100 North America Building
Philadelphia, PA 19107
Telephone: (215) 875-3100

CERTIFICATE OF SERVICE

I hereby certify that I, Steve W. Berman, an attorney, caused a true and correct copy of the foregoing AMENDED MASTER CONSOLIDATED CLASS ACTION COMPLAINT MODIFIED PER THE COURT'S INSTRUCTION AT THE NOVEMBER 21, 2003 HEARING WITH AMGEN AMENDMENTS to be delivered to all counsel of record by electronic service pursuant to Paragraph 11 of the Case Management Order No. 2, by sending on July 8, 2004, a copy to Verilaw Technologies for Posting and notification to all parties

By /s/ Steve W. Berman
Steve W. Berman
HAGENS BERMAN LLP
1301 Fifth Avenue, Suite 2900
Seattle, WA 98101
(206) 623-7292